

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 24
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 10, 2021

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1 PROCEEDINGS had before The Honorable David A. Faber,
2 Senior Status Judge, United States District Court, Southern
3 District of West Virginia, in Charleston, West Virginia, on
4 June 10, 2021, at 9:00 a.m., as follows:

5 THE COURT: Do we have a witness in the
6 courtroom?

7 Mr. Nicholas, did you have some more cross-examination?

8 MR. NICHOLAS: I'm afraid that I do, Your Honor,
9 yes.

10 THE COURT: Good morning, sir.

11 BY MR. NICHOLAS:

12 **Q.** Good morning, Mr. Rannazzisi. How are you?

13 MR. NICHOLAS: Good morning, Your Honor.

14 THE COURT: Good morning.

15 THE WITNESS: Good morning.

16 BY MR. NICHOLAS:

17 **Q.** Do you recall, Mr. Rannazzisi, learning when you
18 took your position in 2005 that AmerisourceBergen
19 personnel had trained DEA diversion investigator
20 trainees at its distribution centers, or center, one of
21 its centers between 1998 and 2005?

22 **A.** I was told during my tenure there that that was to
23 explain to the new diversion investigators how facilities
24 work. So there was training at your facilities, yes, just
25 to explain the overall function of the facility, what the

1 components are of the facility, how the security works,
2 things like that.

3 **Q.** And do you recall that that training occurred on, on a
4 yearly basis --

5 **A.** I can't --

6 **Q.** -- at, at AmerisourceBergen's Richmond distribution
7 center?

8 **A.** I can't be specific on -- that specific. I knew the
9 training occurred.

10 **Q.** Okay. One last question on this. Do you recall that
11 the DEA liaison for those training sessions that
12 AmerisourceBergen gave was none other than the frequently
13 mentioned Mr. Prevoznik in this case?

14 **A.** No, I didn't -- that I didn't know. But Mr. Prevoznik
15 was assigned to training, so that would make sense.

16 **Q.** Okay. Thank you. I'm going to -- I'm now going to go
17 to 2005 and, in particular, the, the distributor initiative
18 meeting that occurred between AmerisourceBergen and the DEA.

19 **MR. NICHOLAS:** So, Ritchie, could you put up,
20 please, Exhibit P-09112 and I'll hand it out. This exhibit
21 has already been admitted in evidence.

22 **May I approach, Your Honor?**

23 **THE COURT:** Yes, you may.

24 **THE WITNESS:** Thank you.

25 **BY MR. NICHOLAS:**

1 **Q.** Now, Mr. Rannazzisi, you were shown this document
2 during direct examination. I'll just begin by asking
3 you again if you recognize the document.

4 **A.** Yes, I do.

5 **Q.** And this is a report that Mr. Mapes submitted to
6 Mr. Walker who at that time was the Deputy Assistant
7 Administrator for the Office of Diversion Control; correct?

8 **A.** That's correct.

9 **Q.** And this report is dated August 16th, 2005; is that
10 correct?

11 **A.** That's correct.

12 **Q.** And it is the report of a meeting that took place at
13 the Office of Diversion Control on August 10th, 2005, which
14 meeting was attended by Mr. Mays, Steve Mays from
15 AmerisourceBergen, Michael Mapes, who was the chief
16 E-commerce section for the DEA, and Kyle Wright who was the
17 chief E-commerce operations. Is that correct?

18 **A.** That's correct.

19 **Q.** And is it correct that the purpose of the meeting was
20 to talk about internet pharmacies?

21 **A.** Internet pharmacies was the basis of the meeting, but
22 it wasn't the concentration -- it was the concentration of
23 the meeting, but it wasn't just about internet pharmacies.

24 **Q.** You didn't -- you did not attend this meeting; is that
25 correct?

1 **A.** No, I did not attend this meeting.

2 **Q.** Okay. Now, if you go to the bullet points on the first
3 page and you go to the, you go to the last bullet point --
4 well, let's start at the beginning. Let's say -- if you go
5 to the top where it says, "Mr. Mapes opened the meeting," it
6 says, "Mr. Mapes opened the meeting by presenting Mr. Mays a
7 PowerPoint briefing which explained the common
8 characteristics of internet pharmacies and why their
9 activities are illegal."

10 Is that right? Did I read that correctly?

11 **A.** That's absolutely correct, yes.

12 **Q.** Now, internet pharmacies at this time period were
13 licensed by the DEA; correct?

14 **A.** No. Brick and mortar pharmacies were licensed by the
15 DEA, pharmacies that would facilitate internet sales, not
16 internet pharmacies. And I think there needs to be --

17 **Q.** Okay.

18 **A.** -- a definition. An internet pharmacy is not
19 necessarily a -- an internet pharmacy encompasses
20 everything. There's internet facilitation sites that then
21 hire brick and mortar pharmacies to fulfill those
22 prescriptions. But, you know, if you're going to define it,
23 it's a brick and mortar pharmacy that's registered, not a,
24 quote/unquote, internet pharmacy.

25 **Q.** So it's the brick and mortar pharmacy that is

1 facilitating these internet pharmacies that you're talking
2 about that is licensed; is that correct?

3 **A.** That's correct.

4 **Q.** Okay. And it says that Mr., that Mr. Mays [sic]
5 reviewed with Mr. Mays, and then it lists a number of bullet
6 points. Do you see that?

7 **A.** Yes.

8 **Q.** And one of the things that Mr. Mapes reviewed with Mr.
9 Mays was bullet point six, example of two internet
10 pharmacies highlighting the brazenness of activity to which
11 internet pharmacies will go to. Do you see that?

12 **A.** Yes.

13 **Q.** And those were -- those -- there's no indication on
14 this document -- and, as a matter of fact, those two
15 internet pharmacies that were being highlighted were not
16 AmerisourceBergen customers. Isn't that, isn't that
17 correct?

18 **A.** Based on this document, I don't know.

19 **Q.** The document doesn't say that they were
20 AmerisourceBergen customers; correct?

21 **A.** It doesn't say that. We would have to go to the Order
22 to Show Cause to see exactly what was said. I believe it
23 was outlined in the Order to Show Cause.

24 **Q.** And I -- the reason I'm asking this is I want to
25 contrast it with what's in the next paragraph.

1 Can we go to the next paragraph, please, and just
2 highlight that paragraph for us.

3 It says -- it starts by saying, "After the presentation
4 Mr. Mays informed representatives of the DEA that
5 AmerisourceBergen does not want to be associated with this
6 type of illegal activity and reviews its customers
7 thoroughly before engaging in business with them."

8 And then it goes on to say, "At this time, Mr. Mays
9 presented a sales profile for," and then it's blocked out so
10 presumably it's the name of a customer, "a pharmacy in
11 Colorado which is allegedly conducting internet sales."

12 Do you see that?

13 **A.** Yes.

14 **Q.** So Mr. Mays was bringing to the DEA's attention an
15 internet pharmacy; correct?

16 **A.** I assume it's a brick and mortar pharmacy.

17 **Q.** Right.

18 **A.** Yes.

19 **Q.** And --

20 **A.** Based on this.

21 **Q.** Yeah. And, so, Mr. Mays was presenting information to
22 the DEA about a brick and mortar pharmacy and presenting
23 some concern -- or suggesting that there was some concern;
24 correct?

25 **A.** He explained what the pharmacy was doing.

1 **Q.** Do you know whether the DEA ever followed up on what
2 essentially was this lead?

3 **A.** I wouldn't know -- I don't even know what the pharmacy
4 is. I mean, it's blocked out. You've got 66,000 pharmacies
5 at that point in time.

6 **Q.** I understand. But this was, this was -- this briefing
7 was -- and this meeting was important to you; is that
8 correct?

9 **A.** It was important to both of us.

10 **Q.** Yes. It was important to you and it was important to
11 AmerisourceBergen; right?

12 **A.** I would hope so, yes.

13 **Q.** Yeah. And, so, I guess I'm asking whether you have a
14 recollection of the fact that Mr. Mays brought this, this
15 pharmacy to the DEA's attention and whether the DEA followed
16 up. Is your answer that you don't recall or you don't know?

17 **A.** I don't -- I can't answer it because I don't know.

18 MR. WESTFALL: Objection.

19 BY MR. NICHOLAS:

20 **Q.** Fair enough. Now, there is nothing in this report
21 that Mr. Mapes submitted to Mr. Walker that says
22 anything about the format or the substance of
23 AmerisourceBergen's suspicious order reports, is there?

24 THE COURT: Mr. Westfall, did that take care of
25 your objection?

1 MR. WESTFALL: I believe so, Your Honor. Sorry.

2 THE COURT: I'm sorry I interrupted you, Mr.

3 Nicholas. Go ahead, please.

4 BY MR. NICHOLAS:

5 Q. Do you recall the question?

6 A. Yes. I'm just reviewing.

7 Q. Sure.

8 A. Thank you. In the memo it doesn't say -- in the memo
9 it doesn't say anything about that.

10 Q. Can you -- can we take a look at the second to last
11 paragraph, please?

12 A. Yes, sir.

13 Q. And in this paragraph what Mr. Mapes reports to
14 Mr. Walker is that, "In consultation with --" and then it's
15 blocked out, "it was agreed that if E-commerce operations
16 (ODCO) were to identify a highly suspicious pharmacy to
17 which AmerisourceBergen was the wholesaler, ODCO would
18 notify AmerisourceBergen via email of the suspicious
19 activity for AmerisourceBergen to review and take the
20 actions the company deems appropriate."

21 Do you see that?

22 A. I do see that.

23 Q. Okay. Did the DEA ever do that, to your knowledge?

24 A. To my knowledge, no, because after, after that was
25 written, when they looked at that particular policy, they

1 decided that there would be due process issues with it. So
2 that -- I don't believe that was ever done.

3 **Q.** Well, let me just break that down. So at the time that
4 Mr. Mapes spoke to Mr. Mays, there was no policy prohibiting
5 just this; is that correct?

6 **A.** Just what?

7 **Q.** The, the -- that the DEA could, could provide to a
8 distributor information -- information regarding suspicious
9 activity at a pharmacy.

10 MR. WESTFALL: Your Honor, I need to object to the
11 question. He can disclose anything that's public
12 information, but he cannot get into attorney/client
13 privileged information or law enforcement investigative type
14 information in regards to this line of inquiry.

15 THE COURT: Well, can you work around that, Mr.
16 Nicholas?

17 MR. NICHOLAS: I think so.

18 BY MR. NICHOLAS:

19 **Q.** Can I -- just to clarify, make sure I understand,
20 Mr. Rannazzisi, are you saying that as a result of this
21 paragraph in this email -- I'm sorry -- in this memo,
22 the DEA changed its policy?

23 **A.** No. What I'm saying is that was a mistake. And the
24 policy has always been that the Department of Justice and
25 DEA would not disclose any type of information like that

1 because of the due process concerns.

2 A pharmacy, any pharmacy, just like any registrant, is
3 entitled to due process. And if you took action because DEA
4 suggested that there might be something, there's a due
5 process issue there. We're very cognizant of due process
6 and respect due process.

7 So if we were just to go and say, "Here's a few
8 pharmacies you should look at," that wouldn't be appropriate
9 and we've always taken that position. I don't know why it
10 was in this memo, but it was inappropriate and it shouldn't
11 have been in there. And if you notice, it wasn't -- I don't
12 believe it was in any other memos.

13 **Q.** I did notice that it wasn't in the other memos, yes.
14 The -- did, did the DEA ever inform AmerisourceBergen that
15 it was, in fact, not going to do what Mr. Mapes said it
16 would do at this meeting?

17 **A.** I don't, I don't have any information regarding that.

18 **Q.** So this was, this was a mistake that Mr. Mapes made at
19 the meeting? Is that your testimony?

20 **A.** My testimony is it's not in line with what the DEA
21 would do. And, so, if -- yeah. It's not -- it's a mistake
22 that it wasn't said. It was a mistake that it was said
23 because it's not in line with DEA's protocols, policies, and
24 procedures and that of the Department of Justice.

25 **Q.** Okay. Let's look at just -- I want to quickly look at

1 the last paragraph of this letter, last sentence and
2 highlight that. "The meeting between --" I'll read it out
3 loud. "The meeting between AmerisourceBergen and DEA was
4 ended at this time with each party having a clearer
5 understanding and agreement as to how best to address the
6 sources of supply to internet pharmacies."

7 Do you see that Mr. Mapes wrote that?

8 **A.** Yes.

9 **Q.** And do you agree with that based on your, based on your
10 knowledge of all this, that both parties, each party came
11 away from this meeting with a better understanding?

12 **A.** I, I would hope so, yes.

13 **Q.** Okay. Now, following this meeting, are you aware that
14 AmerisourceBergen took a number of affirmative steps as a
15 result of the discussions at the meeting?

16 **A.** I was, I was briefed on -- before and after the Orders
17 to Show Cause were issued. So, yes, I was briefed on their
18 systems before and then subsequently what they did.

19 **Q.** And, so, can you agree with me that AmerisourceBergen
20 took affirmative steps in line with DEA's suggestions coming
21 out of that meeting?

22 **A.** I was told that you had altered or changed or modified
23 how you were looking at suspicious orders, yes.

24 MR. NICHOLAS: Ritchie, I apologize. I want to go
25 back to the document for one more minute and look at the

1 PowerPoint.

2 BY MR. NICHOLAS:

3 Q. There was a PowerPoint that was attached to
4 Mr. Mapes' memo; right?

5 A. Yes.

6 Q. Okay. And I just really want to look at the -- first,
7 let's look at the last two pages of the PowerPoint, please.

8 Now, do you recall that attached to your PowerPoint
9 were a list of suggested questions from the DEA that the DEA
10 wanted, was requesting or suggesting that AmerisourceBergen
11 ask its customers as part of a due diligence process?

12 A. Yes. Those -- I don't know if it was part of the
13 PowerPoint, but it was definitely in the presentation.

14 Q. Okay. I believe, unless I'm mistaken, that it was
15 actually attached to the PowerPoint presentation.

16 A. Yeah. It's attached. I didn't know -- I thought you
17 meant it's in the PowerPoint. Yeah. But, no, you're right.

18 Q. Okay. Now, what I'd like to do now is show you the,
19 the due diligence questionnaire that AmerisourceBergen, in
20 fact, developed and put into action as a consequence in part
21 of this meeting. And, so, this is, this is going to be
22 small but let's just --

23 MR. NICHOLAS: Ritchie, we worked on this last
24 night. Let's see if it works. Can you put up -- there you
25 go. I know none of us can see this at all. I should --

1 and, you know, I'm already screwing up my presentations
2 here. Let's start with handing out the PowerPoint
3 presentation.

4 May I approach, Your Honor? I'm sorry.

5 THE COURT: Yes.

6 THE WITNESS: Thank you.

7 BY MR. NICHOLAS:

8 **Q.** Now, to make -- I, I don't want to belabor this
9 because I think we can do it in a pretty straightforward
10 way.

11 If you compare the questions that the DEA suggested
12 with the questions that appear on the form that
13 AmerisourceBergen developed -- and we can do this question
14 by question, but I don't think we have to -- can we agree
15 that AmerisourceBergen used every one of the questions that
16 the DEA suggested in its -- in the form that it developed?

17 **A.** I apologize. I just want to look at the questions.

18 **Q.** That's fine. That's fine.

19 **A.** Yes, a cursory review, it looks like all of the
20 questions were somehow represented in this form.

21 **Q.** And, in fact, AmerisourceBergen added several other
22 additional questions; correct?

23 **A.** It appears that way, yes.

24 **Q.** Okay. Thank you.

25 MR. NICHOLAS: And I guess for the record I should

1 say that the exhibit I've just handed out was Document
2 Number AM-WV-01079. That had also been admitted into
3 evidence already.

4 BY MR. NICHOLAS:

5 **Q.** Now, Mr. Rannazzisi, you just told us that you have
6 learned from briefings that AmerisourceBergen took some
7 additional steps just -- such as this one.

8 Were you also aware that following the 2005 meeting
9 between Mr. Mapes and Mr. Mays, AmerisourceBergen undertook
10 to investigate its pharmacy customers, and not many
11 (verbatim) of its pharmacy customers?

12 **A.** During my time at DEA, I, I believe that was, that was
13 one of the things that they talked about because of the --
14 yeah, I believe that was one of the things they talked
15 about --

16 **Q.** Well --

17 **A.** -- that I was briefed on, yes.

18 **Q.** Okay. I'm just asking a little more than whether -- I
19 don't know who you mean, who talked about it. But were
20 you -- did you come to understand that AmerisourceBergen had
21 undertaken to -- had undertaken investigations of a number of
22 its pharmacy customers?

23 **A.** Not, not necessarily investigations. When I did my --
24 when I took my briefings on this particular --
25 AmerisourceBergen and their particular systems, I was told

1 that they were reviewing their customers. That's -- I
2 don't -- I can't get into more specific than that because
3 that's what I was told.

4 **Q.** Okay. Were you aware that AmerisourceBergen opened
5 investigations to look into the purchasing of hydrocodone
6 and Alprazolam, two of the drugs identified by the DEA in
7 the 2005 meeting?

8 **A.** The extent of what I remember was that
9 AmerisourceBergen was, was reviewing their customer base and
10 looking at their customer base sales. And that's all. I
11 mean, no more than that. I can't remember.

12 **Q.** Okay. Well, we may simply be -- I don't even know if
13 we're disagreeing. We may just be talking about words.

14 **A.** Yeah.

15 **Q.** But were you aware that AmerisourceBergen I'm going to
16 say had opened hundreds of investigations -- you might say
17 was looking into hundreds of its customers -- into both
18 internet and non-internet customers?

19 **A.** I can't put a number on it. I was just advised that
20 they were doing that, you know. I can only tell you so
21 much, and that's about what I remember.

22 **Q.** That's, that's fair. Did you know or did you learn
23 that as a result of the, of these inquiries -- I'll use a
24 softer word -- AmerisourceBergen cut off some of its
25 customers? And I should -- cut off -- ceased to do business

1 with some of its customers.

2 **A.** I seem to remember that was the basis for an email that
3 we had, that I remember, yes. There was customers that were
4 cut off.

5 **Q.** Thank you. All right. Now I'm going to jump to 2007.

6 **A.** Uh-huh.

7 **Q.** The DEA issued an Order to Show Cause on
8 AmerisourceBergen's Orlando facility in 2007, in April of
9 2007; is that correct?

10 **A.** Yes.

11 **Q.** And that resulted in the shutdown of
12 AmerisourceBergen's Orlando facility for a few months; is
13 that correct?

14 **A.** Somewhat. I believe there was some modification to the
15 shutdown. They were allowed to distribute to hospitals at
16 one point in time.

17 **Q.** Right. So three days after the initial shutdown in
18 April, there was a modification which permitted
19 AmerisourceBergen to continue to do business with certain
20 customers; right?

21 **A.** Hospitals, yes.

22 **Q.** Okay. And it was, it was only the Orlando facility
23 that was the subject of the ISO; correct?

24 **A.** That's correct, yes.

25 **Q.** Okay. And the Orlando facility, to your knowledge, did

1 not ship controlled substances to the State of West
2 Virginia, or specifically to Cabell County or to the City of
3 Huntington; correct?

4 **A.** I have no knowledge of that.

5 **Q.** Okay. And do you know of -- therefore, you know of no
6 pills that originated from Orlando, the Orlando facility
7 that went to Cabell or Huntington; correct?

8 **A.** I have no knowledge of any distributions into those
9 counties.

10 **Q.** Okay. And the ISO was triggered by -- had to do with
11 four suspected internet pharmacies; correct?

12 **A.** There were multiple pharmacies. I can't give you the
13 exact figure, but I know there were multiple pharmacies.

14 **Q.** Okay. If I tell you that the number of pharmacies
15 involved, internet pharmacies involved was four, do you have
16 any reason to dispute that?

17 **A.** No, because I knew it was multiple. I just can't give
18 you the exact number.

19 **Q.** Okay. And were you aware or did you become aware that
20 AmerisourceBergen had stopped doing business with three of
21 the four pharmacies that were the subject of the ISO before
22 the ISO was issued?

23 **A.** I don't, I don't remember if they shut down before or
24 not. I can't tell you that.

25 **Q.** Okay. Now, to your knowledge, since this 2007 shutdown

1 of AmerisourceBergen's Orlando facility, has the DEA ever
2 shut down any other AmerisourceBergen distribution center?

3 **A.** To my knowledge, I don't -- I just don't know. I don't
4 have any knowledge of any other shutdown except for that
5 2007.

6 **Q.** Okay. And -- okay. Now, in 2007, later on in June,
7 AmerisourceBergen and the DEA entered into a Settlement
8 Agreement; is that correct?

9 **A.** That's correct.

10 **Q.** And AmerisourceBergen did not pay any fine in
11 connection with that Settlement Agreement; is that correct?

12 **A.** That is correct.

13 **Q.** In fact, to your knowledge, AmerisourceBergen has never
14 paid a fine to the DEA; is that correct?

15 **A.** As far as I know, we've never had a fine from
16 AmerisourceBergen.

17 **Q.** Now, let's take a look at the Settlement Agreement,
18 please, and this is AM-WV-00649.

19 MR. NICHOLAS: May I approach, Your Honor?

20 THE COURT: Yes, you may.

21 MR. NICHOLAS: And we can go right to Page 2 of
22 this agreement, Ritchie, if that's okay.

23 BY MR. NICHOLAS:

24 **Q.** And just quickly, we'll start with Paragraph 2.
25 Just show that bullet out.

1 There was no admission of liability in connection with
2 the Settlement Agreement on the part of AmerisourceBergen;
3 correct?

4 **A.** That's correct.

5 **Q.** Okay. Let's turn to Paragraph 1, subpart (b).

6 Now, this is -- in your testimony on direct, and also
7 on cross, Mr. Rannazzisi, you spoke a number of times about
8 ARCOS data and the fact that there was a time lag, in your
9 view, in terms of the DEA's ability to use ARCOS data
10 because the data was coming weeks or even a month to the DEA
11 after the sales had occurred. Do you remember that
12 testimony?

13 **A.** Yes.

14 **Q.** Okay. That's why I want to look at Paragraph 1(b). In
15 this agreement with AmerisourceBergen, AmerisourceBergen
16 agreed -- let's just look at the first sentence.

17 **A.** Yes.

18 **Q.** "AmerisourceBergen shall, (i), provide to DEA
19 headquarters within two business days following the date of
20 sale a report of all controlled substance transactions
21 through electronic data interchange in a format mutually and
22 reasonably agreed upon by the parties."

23 Do you see that?

24 **A.** Yes.

25 **Q.** Okay. And this information was -- this is not ARCOS

1 reporting that we're talking about now; right? This is
2 something in addition to ARCOS reporting; correct?

3 **A.** If I remember, that's correct, yes.

4 **Q.** And pursuant to this agreement, the DEA was receiving
5 this -- the information about every controlled substance
6 sale that AmerisourceBergen made within two days of the
7 sale; is that correct?

8 **A.** That's what it says, yes.

9 **Q.** Okay. Now, if you go down to the last sentence, it
10 says -- begins with the words "the obligations."

11 "The obligations contained in this paragraph shall
12 remain in full force and effect for a period of five years
13 from the effective date of this agreement, and thereafter
14 shall remain in full force and effect unless terminated and
15 revoked by either party upon 30 days written notice."

16 Do you see that?

17 **A.** Yes.

18 **Q.** The DEA never revoked this term, did it?

19 **A.** I don't believe so.

20 **Q.** And AmerisourceBergen never revoked this term, did it?

21 **A.** Not to my knowledge.

22 **Q.** So since the date of this Settlement Agreement in June
23 of 2007, the DE- -- AmerisourceBergen has been reporting
24 information about every one of its controlled substance
25 sales to the DEA within two days of the sales, of the sale;

1 correct?

2 **A.** Yes, I guess up and to the five-year period, that's
3 probably correct.

4 **Q.** Well, as a matter of fact, that practice continues to
5 this day, doesn't it, Mr. Rannazzisi?

6 **A.** That I don't know.

7 **Q.** Okay. But you do know that it continued at least until
8 2015 when you left the DEA; correct?

9 **A.** No, I don't know that. I just don't know that.

10 **Q.** Do you have any reason to dispute it?

11 **A.** Well, the obligation is for five years. So I, I just
12 don't know. That's something I, I just don't know.

13 **Q.** Well, --

14 **A.** It's raw sales data --

15 **Q.** Right.

16 **A.** -- and it's unreconciled. So they still have to go
17 through the reconciliation process on the raw sales data.
18 It's not ARCOS. It's in addition to ARCOS. But we can't
19 just use raw sales data. We still have to reconcile it to
20 ensure that it's appropriate, it's accurate. So -- and it's
21 not suspicious orders either. It's a -- it's just something
22 that was built into this agreement.

23 **Q.** I assume it was built into the agreement. But correct
24 me if I'm wrong because this was information that the DEA
25 thought would be useful to it; correct?

1 **A.** This is one of those questions I, I don't, I don't
2 necessarily know how this provision got put in this
3 document. So I'm -- it doesn't say whether DEA or whether
4 Amerisource offered it and I -- so I can't really tell you
5 how it got into the document.

6 I do know very specific that it's raw sales data which
7 is not reconciled which means we still have to go through
8 reconciliation to determine if it's accurate.

9 So it's, it's a lot quicker than ARCOS. ARCOS, ARCOS
10 was I think a month -- or I don't remember what your
11 reporting period was. But two days is extremely quick. But
12 it still has to be reconciled. It's still going to be a
13 time lag. And I think that's why in the next section it
14 talks about you still have to report suspicious orders.

15 **Q.** Okay. Just to be clear, because I want the record to
16 be clear on this, this obligation to report within two
17 business days, this data was in effect for at least five
18 years; right?

19 **A.** There's no question that it was in effect for five
20 years.

21 **Q.** Okay. And pursuant to the agreement, it would remain
22 in effect unless someone terminated it with 30 days notice;
23 correct?

24 **A.** That's what the agreement says.

25 **Q.** Okay. And you're not aware that either party did

1 terminate it, are you?

2 **A.** No, I'm not.

3 **Q.** Okay. Let's turn to Page 3 and go to the, to Section
4 2, Paragraph (c), the first full sentence.

5 And without reading the sentence out loud into the
6 record, we can all look at it. The gist is -- correct me if
7 you disagree, Mr. Rannazzisi -- that the DEA agreed to
8 conduct reviews of the functionality of AmerisourceBergen's
9 Diversion Control Program at up to five of
10 AmerisourceBergen's distribution centers as a predicate to
11 the Settlement Agreement.

12 **A.** That's correct.

13 **Q.** Okay. And to put it in plain English, if
14 AmerisourceBergen's distribution centers flunked any of
15 these reviews, there could be -- AmerisourceBergen
16 wouldn't -- there wouldn't be an agreement and
17 AmerisourceBergen wouldn't have gotten its Orlando license
18 back; correct?

19 **A.** Yes, I believe that was the intent.

20 **Q.** Okay. And, to your knowledge, that didn't occur, did
21 it? AmerisourceBergen got its license back in August;
22 correct?

23 **A.** They did get their registration back, yes.

24 **Q.** Okay. So you have no knowledge that there was a
25 problem with any of these reviews; is that correct?

1 **A.** Again, in that snapshot in time --

2 **Q.** Right.

3 **A.** -- when they did that review, no problems were
4 discovered during the inspection.

5 **Q.** All right.

6 **A.** Or if they were, if they were minor problems, they were
7 corrected on-site.

8 **Q.** Last thing on this document. Paragraph -- Page 5,
9 subparagraph (b). This one I'll read out loud.

10 "DEA and AmerisourceBergen shall meet no less than
11 annually at DEA headquarters to discuss, (i), suggestions
12 for improvements in AmerisourceBergen's compliance program
13 to detect and prevent diversion of controlled substances;
14 (ii), any concerns of the DEA related to the sales pattern
15 of controlled substances by AmerisourceBergen; and, (iii),
16 any other issues of concern to either party."

17 Do you see that?

18 **A.** Yes.

19 **Q.** To your knowledge, did the DEA follow up on this and
20 meet with AmerisourceBergen annually?

21 **A.** I, I don't know. I don't recall those meetings, but
22 they would be held by the liaison policy regulatory
23 investigations. And those meetings occur pretty -- you
24 know, people are coming in and out of the building all the
25 time.

1 So I wouldn't -- I don't recall those meetings. They
2 might have happened. They might not have happened. I just
3 don't recall them.

4 **Q.** Okay.

5 **A.** I'm sure that Amerisource, since that's a joint
6 obligation, would have initiated the meeting.

7 **Q.** Do you know whether -- you don't know whether the
8 meetings occurred?

9 **A.** I don't. I don't.

10 **Q.** Okay.

11 **A.** But since it's a joint obligation, --

12 **Q.** Right.

13 **A.** -- it's incumbent on both parties to initiate those
14 meetings.

15 **Q.** Yes. Including the DEA?

16 **A.** Including the DEA, yes. They're one of the parties.

17 **Q.** Okay. Now, yesterday, or maybe it was the day
18 before -- I'm losing track of time here and I'm very close
19 to the end, so -- in your direct --

20 MR. ACKERMAN: Can I interrupt for one minute?

21 MR. NICHOLAS: Absolutely.

22 MR. ACKERMAN: I didn't want to do it while you
23 were doing the document.

24 This, this is a housekeeping matter, but this AM-WV-649
25 is not the version that was admitted into evidence, although

1 it was admitted under an identical P number. So I didn't
2 want to interrupt the questioning. I just wanted to make
3 sure that the record was clear.

4 MR. NICHOLAS: We, we can sort it out afterwards.
5 Thank you.

6 MR. ACKERMAN: You're welcome.

7 THE COURT: Okay.

8 BY MR. NICHOLAS:

9 Q. Now, yesterday -- I'm sorry. I think it was the
10 day before, the day before yesterday on direct
11 examination you testified that one of the ways in which
12 the DEA gave guidance to the industry was through
13 conferences that it, that it hosted or presented to the
14 industry from time to time. Do you recall that
15 testimony?

16 A. Yes.

17 Q. Okay. And a month after this Settlement Agreement was
18 entered into that we just talked about, the DEA sponsored
19 one such conference in Houston, Texas; correct? I'm talking
20 about a September, 2007 conference.

21 A. Yes, there was an industry conference in close
22 proximity to this Settlement Agreement.

23 Q. Now, I'm -- okay. Thanks. I'm going to refer you to a
24 hand-out, another exhibit which has been admitted in
25 evidence. It's Defendants' WV 02191.

1 **A.** Thank you.

2 **Q.** Yep. Do you have it in front of you?

3 **A.** Yes.

4 **Q.** Okay. Just a couple things about this and we don't
5 have to belabor the point. The conference occurred on
6 September 11th and 12th of 2007; correct?

7 **A.** That's correct.

8 **Q.** And what I've given you is the DEA -- a couple of pages
9 from the DEA's website which I believe are actually still --
10 I believe this entry is still up on the DEA's website to
11 this day which, which provides a description of that very
12 conference in September of 2007. Correct?

13 **A.** Yes. For transparency reasons, we put our conference
14 notes -- well, during my time, we put our conference notes
15 up on the website.

16 **Q.** And I want to just direct your attention to two things
17 and they're both on Page 2.

18 MR. NICHOLAS: Thanks, Ritchie.

19 BY MR. NICHOLAS:

20 **Q.** And we can go to -- just go to the section on
21 suspicious orders. Okay. I don't know if there's a way
22 to make that any larger, maybe not. Right?

23 What I want to ask you about, or point out and ask you
24 to confirm is that at this conference, Mr. Mapes, who we've
25 heard so much about from the DEA already, and Mr. Zimmerman

1 from AmerisourceBergen were the co-presenters on the issue
2 of suspicious orders. Do you see that?

3 **A.** Yes.

4 **Q.** Okay. And really just one more thing I want to ask you
5 about. And that is if you go to the second paragraph here,
6 and if I can read it out loud from here, I'll do it. Well,
7 I'll speak very loudly and hope this works.

8 The first sentence reads, "Mr. Zimmerman stressed the
9 importance of knowing your customer and providing due
10 diligence questionnaires [sic] on all new retail and
11 wholesale accounts with the exception of retail chain
12 pharmacies."

13 Do you see that?

14 **A.** Yes.

15 **Q.** Okay. Let's --

16 MR. IRPINO: I just need to object for the record.
17 It says "investigations" and not "questionnaires."

18 MR. NICHOLAS: What did I say?

19 MR. IRPINO: You said "questionnaires."

20 MR. NICHOLAS: I'm sorry.

21 BY MR. NICHOLAS:

22 **Q.** Did I -- let me read it again.

23 "Mr. Zimmerman stressed the importance of knowing your
24 customer and providing due diligence investigations on all
25 new retail and wholesale accounts with the exception of

1 retail chain pharmacies."

2 Do you see that?

3 **A.** Yes, I do.

4 **Q.** Okay. So that, that, along with everything else in
5 this, this, these presentations was part of the guidance
6 that was being transmitted to the industry under the
7 auspices of the DEA at this point in time; correct?

8 **A.** Well, actually, during these conferences we always ask
9 if industry would like to make a presentation. And in this
10 case, Mr. Zimmerman was the presenter that was picked to, to
11 provide information on the industry's behalf.

12 Now, as far as this goes, I guess, yes, it's a, it's a
13 joint presentation, but I think it was mostly
14 Mr. Zimmerman's presentation with Mr. Mapes there.

15 **Q.** Mr. --

16 **A.** Right.

17 **Q.** Right. Mr. Mapes was there and the DEA was represented
18 at the conference; correct?

19 **A.** Absolutely.

20 **Q.** And there was no aspect of any of these presentations,
21 to your knowledge, that the DEA later chose to disavow or
22 correct or anything like that; right?

23 **A.** No. But I do understand this first line, so I
24 understand where he was going with it.

25 **Q.** Okay, all right. Good.

1 MR. NICHOLAS: If I could just have a minute.

2 THE COURT: Yes.

3 (Pause)

4 THE COURT: I've got to switch out court
5 reporters. Are you almost done?

6 MR. NICHOLAS: It's perfect timing because I am
7 done.

8 THE COURT: Okay.

9 MR. NICHOLAS: Mr. Rannazzisi, thank you very
10 much.

11 THE COURT: All right. We'll take our break a
12 little early so we can change court reporters.

13 (Recess taken at 9:52 a.m.)

14 THE COURT: I guess we're back to you, Ms. Singer.

15 MS. SINGER: And, Your Honor, I've learned that
16 the true test -- the true tell, as in a card game, that
17 someone is not going to be brief is to start out by saying
18 I'll be brief. So, I'm not going to say that and hope I
19 will pleasantly surprise you.

20 BY MS. SINGER:

21 **Q.** Mr. Rannazzisi, good morning.

22 **A.** Good morning.

23 **Q.** Do you recall Mr. -- do you recall McKesson's counsel
24 showing you an excerpt from your testimony in your expert
25 deposition in an enforcement action brought by the Ohio

1 Attorney General? Do you remember that yesterday?

2 MR. SCHMIDT: Objection. Objection to
3 characterization of a lawsuit. It's a civil lawsuit. It's
4 not an enforcement action.

5 THE COURT: All right. Sustained. You can
6 re-state the question.

7 BY MS. SINGER:

8 Q. In an action -- I'm sorry. I'll ask the whole
9 question. Do you recall Mr. -- do you recall McKesson's
10 counsel showing you an excerpt from your testimony in your
11 expert deposition in an action brought by the Ohio Attorney
12 General?

13 A. Yes.

14 Q. And he showed you part of the question and answer where
15 he asked you the same question in that deposition. Do you
16 remember being asked about pharmacy registrations?

17 A. Yes.

18 Q. I'd like to show you the rest of that deposition for
19 purposes of completeness.

20 MS. SINGER: Gina, can we cull up --

21 MR. SCHMIDT: Can we get the page, please?

22 MS. SINGER: It is Page 127, Line 12 of Mr.
23 Rannazzisi's deposition. I think we need to go up a little
24 to the start of that question.

25 BY MS. SINGER:

1 **Q.** So, Mr. Schmidt asked you, and I'll read out loud.
2 Well, let me break it down. They say, first, DEA did not
3 conduct background checks on all new applicants. Is that
4 true, that DEA did not conduct background checks on new
5 applicants? Do you recall being asked that question, Mr.
6 Rannazzisi?

7 **A.** Yes.

8 **Q.** And then can you read your response underneath?

9 MR. SCHMIDT: And, Your Honor, I don't believe
10 that impeached Mr. Rannazzisi with this language. I think I
11 asked him a question and he answered without me impeaching
12 him. Am I wrong about that?

13 MS. SINGER: You asked him and showed him part of
14 his answer, but didn't allow him to explain.

15 THE COURT: Go ahead. Overruled.

16 MR. SCHMIDT: I don't believe I showed him this
17 answer, though, just for the record.

18 THE COURT: Okay.

19 BY MS. SINGER:

20 **Q.** So, Mr. Rannazzisi, can you read your answer, please?

21 **A.** Up until 2013, we did -- or '12, we did. But we were
22 using the law enforcement system to run the background
23 checks, and we were told that we were not allowed to use
24 that system for administrative applications, which left us
25 with no way other than relying on the State to ensure that

1 they -- that the states have vetted those applicants in a
2 manner. I can't read the rest of it.

3 **Q.** Do you want to keep going, please?

4 **A.** I can't -- I can't see.

5 **Q.** Oh, I'm sorry. It's an eye test now.

6 **A.** I can't see it's being -- oh, no. It's not moving. We
7 used to run criminal background checks and we were basically
8 advised we can no -- stops there --

9 **Q.** Can you flip the page, please?

10 **A.** -- longer do that.

11 **Q.** And was that testimony that you gave at your expert
12 deposition accurate?

13 **A.** Yes.

14 **Q.** Okay. And let's read the next question and answer, if
15 we could. So, did Mr. Schmidt ask you, okay. So, before
16 2013, did you run criminal background checks on every
17 pharmacy and prescriber applicant for a DEA license? Do you
18 see that question?

19 **A.** Yes.

20 **Q.** And, Mr. Rannazzisi, can you read your response,
21 please?

22 **A.** We used to run background checks on every -- I don't
23 remember if it was -- it might have been earlier than that.
24 There was a decision that came down over that. And what I
25 was saying was basically that it was this decision that

1 required us not to use the -- the criminal databases to --
2 on administrative applications.

3 Q. All right.

4 A. So, at that point in time, we stopped doing it.

5 Q. Okay. And does that accurately reflect DEA's
6 practices?

7 A. Yes.

8 Q. All right. Now, McKesson's counsel also read you part
9 of a paragraph in your congressional testimony regarding 99%
10 of doctors being perfect. Do you recall those questions --
11 that question?

12 A. Yes.

13 Q. Now, you were not asked to read the last sentence of
14 that paragraph. So, I want to pull up 0 -- DEF-WV-00620,
15 please. And let's turn please to Page 98 of the P numbers.

16 So, Mr. Rannazzisi, do you recall reading that 99% of
17 doctors are perfect language yesterday?

18 A. Yes.

19 Q. And can you read aloud the last sentence of that
20 paragraph that you didn't get to look at yesterday?

21 A. What they do is --

22 Q. I think that everyone -- I think that if everybody.

23 A. Oh, yes. I got it. I think that if everybody within
24 the supply chain would just police each other we wouldn't
25 have the problem that we have right now.

1 **Q.** And is that what you said to Congress in 2012 when you
2 testified?

3 **A.** Oh, I've said that numerous times.

4 **Q.** And you may recall that when I started your direct
5 examination, I asked you about the closed system. Do you
6 remember that, that set of questions and answers?

7 **A.** Yes.

8 **Q.** And does that last sentence of your testimony to
9 Congress reflect the purpose of the closed system?

10 **A.** Yes. The closed system -- the closed system is a
11 system of checks and balances. Everybody has an obligation
12 within that system and to -- everybody could -- anybody in
13 that system could stop the action at some point in time and
14 that's why it's a closed system. It prevents diversion.
15 So, everybody has got their own legal obligations and the
16 legal obligations are a system of checks.

17 **Q.** All right. I'd like to turn next to the Federal
18 Register decision of the Acting Administrator in the *Masters*
19 case. Do you remember discussing that with defense counsel
20 yesterday?

21 **A.** Yes.

22 **Q.** So, let's pull up, if we could, DEF-WV-02578. And do
23 you recall being questioned about this document with respect
24 to the three Rannazzisi letters that you've testified about?

25 **A.** Yes.

1 **Q.** All right. Let's turn, please, to the -- to the top of
2 Page 59. Now, you were read the top of Page -- or you may
3 have read the top of Page 9, Mr. Rannazzisi, relating to
4 whether -- let's go to the very top, please, the ALJ did not
5 analyze. First column. There we go.

6 The ALJ did not analyze whether the Rannazzisi letters
7 were intended to, or even could, have binding effect in this
8 proceeding. However, a review of the letters shows that
9 they were not intended to have binding effect but were
10 simply warning letters.

11 Have I read that correctly?

12 **A.** Yes.

13 **Q.** Okay. So, were the -- the Acting Administrator in his
14 decision did not say that the Rannazzisi letters were
15 ineffective, did he?

16 **A.** No.

17 **Q.** And does the opinion say that they were warning
18 letters?

19 **A.** They -- they were simply warning, guidance, warning
20 letters, yes.

21 **Q.** Okay. And let's turn then to the second column, the
22 first full paragraph, and I will read this so you don't have
23 to stand up again.

24 Respondent further argues that the letters do not
25 merely re-state or interpret obligations already present in

1 the regulations, but rather, quote, "supplement DEA
2 regulations with additional and burdensome obligations on
3 registrants" and "represent a fundamental change to the
4 regulations."

5 Do you see where I just read?

6 **A.** Yes.

7 **Q.** And do you understand that to be the position that the
8 registrant was taking in that case?

9 **A.** Yes.

10 **Q.** Okay. And we'll skip over the citations. And the
11 Administrator goes on to say in the final order, thus, it
12 argues that the agency was required to announce the
13 positions taken in the letter by engaging in notice and
14 comment rule making, Respondent's argument is not well
15 taken.

16 Have I read that correctly?

17 **A.** Yes.

18 **Q.** And does that reflect the order of the Acting
19 Administrator?

20 **A.** Yes.

21 **Q.** Did the Acting Administrator in the *Masters* final order
22 agree with the Rannazzisi letters regarding the duty to not
23 ship suspicious orders without conducting due diligence?

24 MR. SCHMIDT: Objection to foundation and
25 characterization. He is not here to give a legal opinion or

1 speak for the Administrator who he has already disagreed
2 with.

3 THE COURT: Well, overruled. I'll let him answer
4 if he can.

5 THE WITNESS: I believe there was -- in the
6 *Masters* decision there was a discussion on the do not ship
7 as related to maintaining effective controls against
8 diversion.

9 AND MS. SINGER:

10 **Q.** And are you aware that the Acting Administrator's
11 finding on the shipping duty was affirmed by the D. C.
12 Circuit in the *Masters* decision, in its *Masters* decision?

13 **A.** I -- that, I just don't recall. I believe that the DC
14 court did address -- discussed the do not ship requirements,
15 but I don't recall what their decision was regarding the do
16 not ship portion of the policy.

17 **Q.** Okay. All right. We can put this one away.

18 Now, McKesson's counsel also asked you if you are aware
19 that McKesson's anti-diversion program or its compliance
20 program evolved during your tenure. Do you recall that line
21 of questioning?

22 **A.** Yes.

23 **Q.** And you indicated that you were aware that there were
24 changes in McKesson's policies; is that right?

25 **A.** That's correct.

1 Q. Now, are you aware that after you left the DEA in 2017
2 that McKesson entered into another Settlement Agreement with
3 the DEA?

4 MR. SCHMIDT: Objection. This is well outside the
5 scope of anything I covered and by admission of the question
6 outside his time period.

7 THE COURT: I'm going to let him answer. Go
8 ahead. Overruled.

9 THE WITNESS: Yes. I'm aware of an agreement
10 reached with the government with McKesson.

11 MS. SINGER: All right. Sorry. Can we pull out
12 P-00013?

13 May I approach, Your Honor?

14 THE COURT: Yes.

15 MR. SCHMIDT: Your Honor, we'll renew our
16 objection now that we're going to walk through a whole new
17 exhibit that was never covered in my questioning. Also,
18 this is outside the scope of the MDL deposition where he
19 said he'd never reviewed this.

20 THE COURT: What about that, Ms. Singer?

21 MS. SINGER: Two reasons that I request to use
22 this document, Your Honor.

23 The first is that it relates to conduct that I believe
24 happened during Mr. Rannazzisi's tenure and I will attempt
25 to lay a foundation about that so it's not asking him about

1 issues that occurred or conduct that occurred after he left
2 the DEA.

3 Second, my intention is not to walk through this entire
4 document but to focus on one provision related to the
5 Rannazzisi letters which Mr. Schmidt explored in his cross
6 examination.

7 THE COURT: Overruled. Go ahead.

8 MR. SCHMIDT: And, Your Honor, may I just read
9 into the record the deposition testimony? Were you aware of
10 this agreement before I handed it to you? No. I have never
11 seen this agreement before you handed it to me. That's his
12 testimony in the MDL deposition 476, Page 5 -- Line 5
13 through 10. So, we object on both scope and outside of the
14 -- his foundation and the agreement on his testimony from
15 plaintiffs.

16 THE COURT: Where are you going here, Ms. Singer?

17 MS. SINGER: Again, Your Honor, I just want to ask
18 Mr. Rannazzisi about one paragraph that relates to the
19 Rannazzisi letters which Mr. Schmidt explored at length and
20 about conduct that happened during Mr. Rannazzisi's tenure.

21 THE COURT: All right. Overruled. You can ask
22 him.

23 BY MS. SINGER:

24 Q. All right. Mr. Rannazzisi, can you turn to Page 2 --
25 I'm sorry -- Page 3 of the document? Now, do you recall

1 when McKesson entered into its first Memorandum of Agreement
2 or Settlement Agreement with DEA?

3 **A.** I believe it was sometime in 2008.

4 **Q.** Okay. All right. So, let's look at Paragraph 2. I'm
5 going to read this out loud to you. On or about
6 September 27th, 2006, February 7, 2007, and December, 2007
7 -- I'm sorry -- December 27th, 2007, DEA's Deputy Assistant
8 Administrator, Office of Diversion Control, sent letters to
9 every entity in the United States that was registered with
10 DEA to manufacture or distribute controlled substances,
11 including McKesson. (The DEA letters).

12 Have I read that correctly?

13 **A.** Yes.

14 **Q.** The DEA letters contained, among other things, guidance
15 for the identification and reporting of suspicious orders to
16 DEA, as required by 21 CFR Section 1302.74(b).

17 Have I read that correctly?

18 **A.** Yes.

19 **Q.** And in the next sentence does McKesson acknowledge
20 that, at various times during the period from January 1st,
21 2009, up through and including the effective date of this
22 agreement, the covered time period, it did not identify or
23 report to DEA certain orders placed by certain pharmacies
24 which should have been detected by McKesson as suspicious
25 based on the guidance contained in the DEA letters about the

1 requirements set forth in 21 CFR 1301.74(b) and 21 USC
2 Section 842(a)(5)?

3 Have I read that correctly?

4 **A.** Yes.

5 MR. SCHMIDT: Your Honor, this is our objection.
6 We're just reading portions of a document that's been use
7 with other witnesses in the evidence and that had nothing to
8 do with my exam.

9 THE COURT: You can use it as a basis to ask him
10 questions, but --

11 MS. SINGER: And so, I'm going to --

12 THE COURT: -- reading it into the record --

13 MS. SINGER: So, Your Honor, I'm sorry. I just
14 wanted to get that piece of it out so that I could ask Mr.
15 Rannazzisi.

16 BY MS. SINGER:

17 **Q.** Do you understand that McKesson acknowledged that it
18 failed to follow the guidance in your three guidance letters
19 or warning letters to registrants?

20 **A.** Yes. According to that, yes.

21 **Q.** All right. No further questions on this document.
22 So, let's turn to P-19418, please.

23 May I approach again, Your Honor?

24 BY MS. SINGER:

25 **Q.** Now, Mr. Rannazzisi, do you recall discussing, I think

1 at some length over the last two days, Excessive Purchase
2 Reports?

3 **A.** Yes.

4 **Q.** Now, do you -- looking at the cover page of P-19418, do
5 you recognize the individuals to and from whom this e-mail
6 was sent?

7 **A.** Yes.

8 **Q.** And who sent this e-mail?

9 **A.** Kyle Wright.

10 **Q.** Okay. And was it sent from his DEA e-mail?

11 **A.** Yes. Yes.

12 **Q.** And what is the date of the e-mail?

13 **A.** August 12th, 2005.

14 **Q.** Okay. And so, that's before the date of the revision
15 to the Diversion Investigator Manual in 2010, correct?

16 **A.** That's correct.

17 **Q.** So, I'd like you to take a moment and look at this
18 document and, in particular, to turn to the second page.

19 **A.** Okay.

20 **Q.** Do you recognize the document that begins at the second
21 page?

22 **A.** Yes.

23 **Q.** And what do you recognize it to be?

24 **A.** It's just an -- it's an internet pharmacy briefing.

25 **Q.** And was the date of the presentation?

1 **A.** August 10th, 2005.

2 **Q.** And to whom was the presentation made?

3 **A.** It was made to AmerisourceBergen.

4 **Q.** And so, does this represent the distributor initiative
5 briefing with AmerisourceBergen that Mr. Nicholas asked you
6 about earlier this morning?

7 **A.** Yes. This is -- this is a distributor initiative
8 PowerPoint part of the briefing, yes.

9 **Q.** And you testified that prior to launching the
10 distributor initiative you were briefed on guidance that DEA
11 had previously provided to registrants; is that correct?

12 **A.** That's correct.

13 **Q.** Oops, I'm sorry. I skipped ahead. Sorry.

14 Are these the slides -- I'm sorry. I've asked you
15 that.

16 I don't know how adept you are at PowerPoint, but do
17 you recognize that this version has speaker notes to it?

18 **A.** Yes. I'm familiar with PowerPoint and, yes, I've seen
19 the speaker notes.

20 **Q.** Okay. Let's turn to Page 13, if we could. And this is
21 the slide on suspicious orders, is it not?

22 **A.** Yes.

23 **Q.** And what does the speaker note on that slide say?

24 **A.** Suspicious --

25 MR. NICHOLAS: Your Honor, I'll object on hearsay

1 grounds with regard to the speaker notes. Mr. Rannazzisi
2 was not at the meeting. He doesn't know what was said.

3 THE COURT: Well, I'll let you ask him about it,
4 Ms. Singer, and we'll see whether he knows anything about it
5 or not. Go ahead.

6 MS. SINGER: Thank you, Your Honor.

7 BY MS. SINGER:

8 **Q.** Do you recognize the speaker note at the bottom of this
9 slide?

10 **A.** I've never seen the presentation with speaker notes,
11 no. I've never seen -- this is the presentation, but I've
12 never seen it with the speaker notes.

13 **Q.** Okay. And did you discuss with your staff prior to the
14 briefing what they would be saying with respect to this
15 slide on suspicious orders?

16 MR. NICHOLAS: I'll renew my objection.

17 THE COURT: Yes. I will sustain it that time, Ms.
18 Singer. He said he hadn't seen it and doesn't know anything
19 about it.

20 MS. SINGER: Understood, Your Honor. All right.
21 Let's move on from this document.

22 Let's turn to P-15925 [sic] -- I'm sorry -- 19525.

23 May I approach, Your Honor?

24 BY MS. SINGER:

25 **Q.** All right. Mr. Rannazzisi, do you have P-19525 in

1 front of you?

2 **A.** Yes.

3 **Q.** And do you recognize the name Gene Haislip?

4 **A.** It's Gene Haislip.

5 **Q.** Haislip. I'm sorry.

6 **A.** Yes.

7 **Q.** And who is Gene Haislip?

8 **A.** Gene Haislip was the Director of the Office of
9 Diversion Control for quite a few years in the 70s and 80s.

10 **Q.** And so, he was one of your predecessors; is that right?

11 **A.** That's correct.

12 **Q.** And to whom is this addressed?

13 **A.** It's addressed to Phil Jordan.

14 **Q.** And do you recognize that name?

15 **A.** Yes. He was a special agent in charge of the Dallas
16 Field Division a long time ago.

17 **Q.** And do you see a date on this document?

18 **A.** December 8th, 1993.

19 **Q.** And I'm going to ask you again the question that I
20 wrongly asked you out of order before. Now, you testified
21 that prior to launching the distributor initiative you were
22 briefed on guidance that DEA had previously provided to
23 registrants; is that correct?

24 **A.** Yes.

25 **Q.** And were you aware of a letter sent from the Office of

1 Diversion Control regarding Excessive Purchase Reports?

2 **A.** Yes. I was -- I was told that there were -- there was
3 a letter that was sent at one point in time from I believe
4 they said Terry Woodworth that addressed Excessive Purchase
5 Reports.

6 **Q.** And do you believe that this was the letter that you
7 were briefed on?

8 **A.** Yes.

9 **Q.** And why is that?

10 MR. SCHMIDT: And, Your Honor, I think they need
11 to establish that he's seen this letter. Terry Woodworth
12 doesn't appear on the face of this letter. This is an
13 internal DEA memo that I don't believe Mr. Rannazzisi ever
14 saw.

15 THE COURT: All right. Can you clear that up, Ms.
16 Singer?

17 MS. SINGER: Absolutely.

18 THE COURT: Otherwise, I will sustain the
19 objection.

20 MS. SINGER: Absolutely.

21 BY MS. SINGER:

22 **Q.** So, why do you believe, Mr. Rannazzisi, that this is
23 the letter that you were referred to?

24 **A.** Because Terry Woodworth was one of the execs during
25 that time period in the Office of Diversion Control and

1 Terry did a lot of -- of the correspondence and that's why I
2 think I was told it was a Terry Woodworth letter.

3 **Q.** Okay. And do you believe this letter to be -- to
4 reflect the official position of the DEA in 1993?

5 MR. SCHMIDT: Your Honor, he's now testifying
6 about a letter he still hasn't -- or a memo. He still
7 hasn't said he saw this memo.

8 THE COURT: Correct. Right. Sustained.

9 BY MS. SINGER:

10 **Q.** Have you seen this memo previously?

11 **A.** No. I have not seen this particular memo previously.

12 **Q.** And do you believe that the guidance it refers to
13 regarding Excessive Purchase Reports is consistent with the
14 guidance that you were briefed on when you began the
15 distributor initiative?

16 MR. SCHMIDT: Objection, foundation. Objection,
17 hearsay.

18 THE COURT: I'll sustain the objection, Ms.
19 Singer. You can ask him about his understanding of what the
20 guidance was at that time, if he knows, but this was -- this
21 is almost ancient history here, isn't it? I will sustain
22 the objection.

23 MS. SINGER: For some of us, it feels like
24 yesterday.

25 BY MS. SINGER:

1 Q. Mr. Rannazzisi, do you -- do you recall what the
2 position of -- and did you come to know the position of the
3 DEA in the early 90s, many, many years ago, about whether
4 Excessive Purchase Reports were sufficient and satisfied
5 registrants' obligations?

6 MR. SCHMIDT: Objection, foundation and hearsay.
7 The only way he said he knows is not by actually reviewing
8 documents or documentary evidence, but by some amorphous
9 briefing. That's pure hearsay. And it's untestable. The
10 problem with it is it's untestable on our side.

11 THE COURT: And that was before he was in a
12 position of authority over this or anything related to it.

13 MS. SINGER: So --

14 MR. WESTFALL: Your Honor, for the United States,
15 again, if it's any communications, if this testimony is
16 going to be based on any communications from counsel, it
17 would be -- it would basically be privileged under
18 attorney-client privilege. And so, he can't disclose
19 anything to be non-public in connection to this.

20 MR. SCHMIDT: At that particularly stymies us,
21 Your Honor, because they're trying to have him say I was
22 told this and we can't ask about it and we don't even have a
23 basis for challenging it because of such hearsay.

24 THE COURT: Well, if you can lay a foundation that
25 he had knowledge of what the policy was at this time, then

1 you can ask him about the policy, but the letter is --
2 there's no connection that I can see between the letter and
3 this witness.

4 MS. SINGER: So --

5 THE COURT: But it can give you a good faith basis
6 to ask him about the point at issue here, it seems to me, if
7 you can establish that he was in a position and had
8 knowledge about it at that time.

9 BY MS. SINGER:

10 Q. So, Mr. Rannazzisi, when you were briefed after
11 becoming Deputy Assistant Administrator and starting the
12 distributor initiative, were you -- did you come to learn of
13 the DEA's position in the early 90s with respect to whether
14 Excessive Purchase Reports were sufficient -- were
15 sufficient and satisfied registrants' obligations under --
16 under 1301.74?

17 MR. SCHMIDT: I think the question is literally
18 asking for hearsay. So, we object on hearsay.

19 MS. SINGER: Your Honor, again, what I am
20 attempting to do, no doubt unartfully, is establish that Mr.
21 Rannazzisi learned about this policy and then made sure that
22 his guidance was consistent with his past policy, which is
23 what he's testified to.

24 THE COURT: Well, if he learned about the policy
25 through what somebody told him, then -- then it is hearsay,

1 isn't it?

2 MS. SINGER: Your Honor, I think for the purpose
3 that I'm attempting to illicit this testimony, which is --
4 I'm going to take a lifeline from Mr. Irpino, if that's
5 okay.

6 MR. SCHMIDT: We'll object to that, Your Honor.
7 We object to the multiple objectors on behalf of the same
8 entities from the same firm.

9 MR. IRPINO: I'm not from the same firm, Mr.
10 Schmidt.

11 MR. SCHMIDT: Okay. Then my mistake.

12 MR. IRPINO: Thank you because that is an honor.

13 THE COURT: Well, don't argue with each other. If
14 you want to argue, have an argument, you've got to have it
15 with me.

16 MS. SINGER: I'm sorry.

17 MR. IRPINO: Yes, Your Honor. Anthony Irpino on
18 behalf of Cabell County from Irpino Avin & Hawkins.

19 THE COURT: Okay. I'm going to sustain the
20 objection to this and you can move on, Ms. Singer.

21 MR. IRPINO: Your Honor, for the record, we would
22 just offer that this does not satisfy 801(c)(2) as not being
23 offered for the truth of the matter but, rather, for state
24 of mind, what the witness had, and notice. We just need to
25 make our record.

1 THE COURT: You can put your position on the
2 record. I respectfully disagree with it and I've already
3 put my reason for the ruling on the record.

4 Go ahead, Ms. Singer, to your next point.

5 MS. SINGER: Let's turn to P-23699, please.

6 May I approach, Your Honor?

7 THE COURT: Yes.

8 BY MS. SINGER:

9 Q. Mr. Rannazzisi, do you recognize the document that I've
10 just handed you?

11 A. Yes.

12 Q. And what do you recognize it to be?

13 A. This is a PowerPoint presentation that's done during
14 the PDAC, which is the Pharmacy Diversion Awareness
15 Conference.

16 Q. And do you recall yesterday that defense counsel showed
17 you certain slides from this presentation?

18 A. Yes.

19 Q. Okay. And do you recognize this as the full
20 presentation?

21 A. It looks to be the full presentation.

22 Q. And is this a presentation that you gave as Deputy
23 Assistant Administrator during your tenure at DEA?

24 A. Yes.

25 Q. And this PowerPoint was given in March of 2013; is that

1 right?

2 **A.** Yes. That's what it's dated.

3 **Q.** And did you give this presentation on other occasions,
4 as well?

5 **A.** Yes. Variations. This is a cut-down version of the
6 full presentation but, yes, variations of this presentation,
7 I've given throughout the country numerous times to -- this
8 is the PDAC, so it would be the pharmacies -- or pharmacists
9 and techs and people from industry in the area where the
10 PDAC occurs.

11 **Q.** And do you know whether this presentation -- I'm sorry.

12 MS. SINGER: I move to admit, Your Honor, the full
13 version of this March, 2013 DEA PowerPoint given by Mr.
14 Rannazzisi.

15 MR. SCHMIDT: Object as hearsay, Your Honor.

16 THE COURT: How do you get around the hearsay, Ms.
17 Singer?

18 MS. SINGER: So, Your Honor, I believe that this
19 is admissible pursuant to Rule 803(8) as a public record.
20 Mr. Rannazzisi authenticated it as a DEA document. In fact,
21 this PowerPoint is publicly available on the DEA's website
22 right now. I'm happy to provide the website address for
23 that.

24 Further, excerpts of the document were partially
25 introduced yesterday by reading limited portions into the

1 record. The complete version should now be submitted, as
2 well. But, again, stand on the fact that this is a public
3 record, Your Honor.

4 MR. SCHMIDT: Two responses, Your Honor. Ms.
5 Singer is correct that I did use, I think, three slides or
6 two slides from this, but they were used solely for the
7 purpose of impeachment. I didn't move it into evidence.
8 So, that doesn't open up the whole document any more than it
9 would any other impeachment source.

10 As to the public record, that argument would allow any
11 public record. This is not a public record. It is a
12 presentation he gave to pharmacies. The fact that he gave a
13 presentation does not make it a public record within the
14 requirements of Rule 803(8), none of which were specifically
15 invoked.

16 I would also note that yesterday the plaintiffs
17 successfully objected to an actual letter from the DEA to
18 the General Accountability Office as not a public record.
19 That's certainly much more heartland a public record than a
20 slide presentation given to pharmacists in New Mexico.

21 THE COURT: Well, I'm not going to admit it as a
22 public record and I don't think -- I think since it was just
23 used as an impeachment source, I don't think you're entitled
24 to admit the whole thing under the Rule of Completeness, but
25 if there are parts of it that you want to use as a basis to

1 question him, I'll let you do that.

2 MS. SINGER: Your Honor, may I have a moment?

3 (Pause)

4 MS. SINGER: All right. I'll move on, Your Honor.

5 BY MS. SINGER:

6 **Q.** Mr. Rannazzisi, when you were talking about the few
7 slides that defense counsel showed you, I think you -- you
8 testified about the source of drugs that are diverted and
9 how much of diversion related to drug -- to opioids obtained
10 from friends and family. Do you recall that testimony?

11 **A.** Yes.

12 **Q.** And do you recall a conversation you had or questions
13 and answers with defense counsel about whether your
14 testimony represented the administrative -- Administrations'
15 position on that issue?

16 **A.** Yes.

17 **Q.** And do you recall that you testified that it was your
18 view that the Administration's position was inaccurate?

19 **A.** I said I didn't agree with it.

20 **Q.** Didn't -- I'm sorry.

21 **A.** I didn't agree with it because it's based on a survey.

22 **Q.** And do you recall -- also recall that you testified
23 that you based that view on your experience with
24 investigations at the DEA?

25 **A.** That's correct.

1 **Q.** And can you explain what investigations you were
2 referring to?

3 **A.** Large scale diversion investigations where we saw
4 people going into or purchasing pharmacies over the
5 internet, purchasing drugs over the internet in large
6 quantities, and also purchasing -- going down into Florida
7 and other states, going to pain clinics and purchasing huge
8 quantities, and then bringing them back. Obviously, that is
9 -- that's how diversion occurs and I just don't think the
10 survey captured that. And that survey is a yearly survey
11 and it just doesn't capture the extent of diversion.

12 **Q.** You testified also, I think this morning and late
13 yesterday, about -- about an early Suspicious Order
14 Monitoring System by Bergen Brunswig. Do you recall being
15 questioned on those Zimmerman letters also from long ago in
16 the 90s?

17 **A.** Yes.

18 **Q.** And during your tenure from 2005 until you retired did
19 anyone ever tell you that Bergen Brunswig's Suspicious Order
20 Monitoring System had been approved by DEA?

21 **A.** No one ever told me that there was any approval, be it
22 Bergen Brunswig, or any other system. No one ever advised
23 me that a system was approved.

24 **Q.** And in advance of the 2006 Order to Show Cause that you
25 signed off onto the Deputy Administrator were you briefed on

1 -- were you briefed by your staff on DEA's investigation of
2 AmerisourceBergen?

3 **A.** Yes.

4 **Q.** And in those briefings, did you ever learn that DEA had
5 signed off on AmerisourceBergen's Suspicious Order
6 Monitoring System?

7 **A.** No.

8 **Q.** And do you expect that your staff would have told you
9 of that before you signed off on the Order to Show Cause?

10 MR. NICHOLAS: I'll object to that question as
11 speculative.

12 THE COURT: Well, overruled. You can answer, if
13 you can, Mr. Rannazzisi.

14 THE WITNESS: Thank you, Judge.

15 Yes, I would have expected that that would have been
16 brought up.

17 BY MS. SINGER:

18 **Q.** All right. Let's turn back to P-00016. So, Mr.
19 Rannazzisi, it's a long document. I'm not going to show you
20 again. It's in the matter of McKesson -- McKesson
21 Corporation, the file related to the Order to Show Cause
22 against McKesson in 2006 and I just want to refer you to one
23 -- one page, which was shown to you both by Mr. Schmidt and
24 by me. So, let's turn to Page 139. And, again, this is
25 P-00016.

1 Mr. Rannazzisi, do you recall that McKesson's counsel
2 read you the proposed testimony of Mr. Mahoney of McKesson
3 in that proceeding?

4 **A.** Yes.

5 **Q.** And I want to turn -- so now, at Page 139, do you see
6 your name under proposed testimony?

7 **A.** Yes.

8 **Q.** And can you -- you know what? I'm going to save you
9 and read it quickly. But it said that you would testify
10 regarding your professional background and experience, that
11 you -- that he met with McKesson officials in January 2006
12 regarding McKesson's extraordinarily large distributions of
13 hydrocodone, and select other controlled substances to
14 pharmacies under circumstances that indicated that the
15 pharmacies were diverting controlled substances, that he
16 asked the McKesson representatives if they could give him
17 any reason why DEA should not revoke McKesson's registration
18 and McKesson officials did not explain why their large
19 distributions to pharmacies under suspicious circumstances
20 and, three, that after the January 2006 meeting, McKesson
21 continued to distribute controlled substances under
22 circumstances that were indicative of diversion.

23 And then it goes onto the national problem regarding
24 the diversion of hydrocodone and benzodiazepines and the
25 efforts that DEA has taken to educate distributors about the

1 warning signs of diversion, and the efforts that DEA took to
2 educate McKesson.

3 Have I read that accurately?

4 **A.** Yes.

5 **Q.** And does that reflect the testimony that you would have
6 given if called to testify at an Order to Show Cause
7 hearing?

8 **A.** Absolutely.

9 **Q.** All right. We can put this document down.

10 You testified that after the second meeting with --
11 between McKesson and DEA on January 3rd, 2006, that McKesson
12 acknowledged to DEA that its Suspicious Order Monitoring
13 System was not monitoring generic hydrocodone; is that
14 right?

15 MR. SCHMIDT: Objection. Leading and
16 characterization.

17 THE WITNESS: McKesson informed --

18 MR. SCHMIDT: Your Honor, there is a pending
19 objection. Unless Your Honor ruled on it.

20 THE WITNESS: I apologize, Your Honor.

21 THE COURT: Just a minute. Well, it is leading.
22 I'll sustain the objection to the leading question, but if
23 you can ask him without leading him, go ahead.

24 MS. SINGER: All right.

25 BY MS. SINGER:

1 Q. Mr. Rannazzisi, do you recall testifying about
2 information you received at DEA about whether McKesson was
3 monitoring its distribution of generic hydrocodone?

4 A. Yes.

5 Q. And do you recall Mr. Schmidt asked you whether you
6 were familiar with testimony from Mr. Hilliard of McKesson
7 that -- that McKesson's failure to look at generic
8 hydrocodone was an acute and not a chronic problem? Do you
9 recall that question and answer?

10 A. Yes. I recall that question.

11 Q. And do you recall Mr. Schmidt asking you if you were
12 aware of a presentation of correspondence that McKesson
13 provided to DEA I think through Linden Barber?

14 A. I -- could you please repeat the question?

15 Q. Yes. Do you recall Mr. Schmidt asking you about
16 whether McKesson conveyed to DEA presentations or materials
17 about its -- its controlled substance monitoring program?

18 A. Yes. I believe that was the case, yes.

19 MR. ACKERMAN: Ms. Singer, may I interrupt for a
20 moment?

21 Your Honor --

22 MS. SINGER: Are you objecting to me?

23 MR. ACKERMAN: I am not objecting to you.

24 Your Honor, I don't know if the Court has noticed.

25 There is a lot of rustling happening on the other side and I

1 think because the microphones are on, the microphones are
2 picking it up. It is a little bit distracting, so I --
3 since I'm not going to speak to counsel directly, I would
4 make the request of the Court that counsel try to keep their
5 movements to a minimum during our questioning, as we have
6 done during their questioning.

7 MR. SCHMIDT: I'm not sure -- we've had it on both
8 sides, but I hear what they're saying and we'll try to do
9 that. It's one of these challenges of these documents kind
10 of flying by and we're trying to locate which documents they
11 had.

12 THE COURT: I understand that. That's --

13 MR. SCHMIDT: But we'll certainly do that, Your
14 Honor.

15 THE COURT: Okay.

16 Go ahead, Ms. Singer.

17 BY MS. SINGER:

18 Q. All right. Let's turn, if we could, to P-00098.

19 May I approach, Your Honor?

20 THE COURT: Uh-huh.

21 THE WITNESS: Thank you.

22 THE COURT: This is the half hour you were going
23 to do yesterday at the close of the day; is that right?

24 MS. SINGER: I'm sorry, Your Honor. I remember I
25 made no promises this morning, but I am nearly at the end.

1 THE COURT: Well, that's true. That is true. But
2 you now know why I cut it off yesterday.

3 Go ahead, please.

4 MS. SINGER: But it only gave me more time, Your
5 Honor, to cogitate on this.

6 BY MS. SINGER:

7 Q. Mr. Rannazzisi, have you seen this document before?

8 A. Not during my time at DEA.

9 Q. Okay. And were you aware that McKesson had conducted
10 an audit of its order monitoring system in 2007 and found
11 that it was still not sure that its system was picking up
12 generic drugs?

13 MR. SCHMIDT: Your Honor, I think what's happening
14 is the witness is being asked a question as he's reading a
15 document he literally says he never saw. I don't think
16 that's appropriate questioning.

17 MS. SINGER: I'm just --

18 MR. SCHMIDT: And I think at least the document
19 should be taken back so the witness isn't giving testimony
20 based on the document. If she wants to pose him a question
21 interrelated to the document and whether he knows it, that's
22 fine, but it's unfair for him to have it in front of him and
23 leading by document.

24 THE COURT: Well, I agree with that, Ms. Singer.

25 MS. SINGER: All right. May I approach again?

1 THE COURT: Yes, you may.

2 BY MS. SINGER:

3 Q. So, Mr. Rannazzisi, with no document in front of you
4 are you aware that McKesson conducted an internal audit of
5 its controlled substance monitoring system in 2007 and found
6 that it was still not sure that its system was picking up
7 generic drugs?

8 MR. SCHMIDT: Objection, foundation.

9 THE WITNESS: I know that they -- I know that they
10 conduct --

11 THE COURT: You have to lay a foundation.

12 THE WITNESS: Oh, I apologize.

13 THE COURT: If he had personal knowledge, Ms.
14 Singer. If you can do that, I'll let you go ahead.

15 MS. SINGER: Excuse me one second, Your Honor.

16 (Pause)

17 BY MS. SINGER:

18 Q. So, Mr. Rannazzisi, I'm sorry. I hadn't heard. What
19 do you -- what do you know about McKesson conducting
20 internal audits?

21 A. I was just told that they were reviewing their systems
22 during my briefings and I don't recall exactly whatever they
23 were doing, but I do recall during my briefings that they
24 were reviewing their internal systems.

25 Q. And did you learn during those briefings that McKesson

1 had discovered in one of those internal audits that it was
2 not sure in 2007 that its system was picking up generic
3 controlled substances?

4 **A.** I don't recall. I don't recall that being relayed to
5 me in 2007.

6 MS. SINGER: Okay. Let's turn to P-42653.

7 May I approach, Your Honor?

8 BY MS. SINGER:

9 **Q.** Mr. Rannazzisi, can you turn to Page 2 of this
10 document?

11 **A.** Yes.

12 **Q.** And do you see your name among the participants listed
13 in this document?

14 **A.** Yes.

15 **Q.** And what is the -- what is this -- what does this
16 document refer to?

17 MR. SCHMIDT: Objection, foundation. This is an
18 internal McKesson document. The fact that he was at the
19 meeting doesn't give him a foundation to testify about this
20 document.

21 THE COURT: Overruled. We'll see where this goes.
22 Go ahead, Ms. Singer.

23 BY MS. SINGER:

24 **Q.** Mr. Rannazzisi, I think I had asked you what the date
25 was.

1 **A.** September 19th, 2007.

2 **Q.** And do you recall a meeting that you participated in on
3 that date between McKesson and DEA?

4 **A.** I participated in so many meetings and briefings. If
5 you're asking me do I recall the specifics of this meeting,
6 no, but I know I've been involved in meetings like this over
7 and over again and my name is on there, so I'm sure I was
8 there. I just don't recall this particular meeting.

9 **Q.** Okay. And do you recall a meeting at which you
10 discussed with McKesson what DEA would expect in a
11 resolution of its Order to Show Cause?

12 MR. SCHMIDT: I think he's already said he doesn't
13 recall this meeting. At a minimum, he shouldn't be
14 testifying off of this document.

15 THE COURT: Well, the question has moved to just a
16 general question, whether he recalled a meeting. I don't
17 think that question relates to this specific meeting
18 necessarily. So, I'll overrule the objection and let him
19 answer the question.

20 MR. SCHMIDT: Understood, Your Honor.

21 May I ask the document be withdrawn?

22 THE COURT: Yes. Yes.

23 MS. SINGER: Thank you.

24 BY MS. SINGER:

25 **Q.** Mr. Rannazzisi, do you remember the question?

1 **A.** Could you repeat the question really quickly?

2 **Q.** Yes. Do you recall a meeting between DEA and McKesson
3 to discuss what DEA would expect in an agreement or a
4 settlement to resolve the Order to Show Cause?

5 **A.** I recall meetings to discuss -- to discuss what's to be
6 expected. I don't recall a particular meeting with
7 McKesson. I know there were internal meetings at DEA that
8 discussed that. I'm just not sure if McKesson was there at
9 the time. I just don't recall that.

10 **Q.** Okay. We'll move on from that.

11 Mr. Rannazzisi, do you recall questions that you were
12 asked by Cardinal's counsel about the elements of the
13 regulatory elements of what constitutes a suspicious order?

14 **A.** Yes.

15 **Q.** And can we cull up the demonstrative on 1301, please?
16 And Ms. Wicht, I think, asked you about the last sentence of
17 the regulation which defines suspicious orders. Can you
18 read the first sentence of that regulation?

19 **A.** The registrant shall design and operate a system to
20 disclose to the registrant suspicious orders of controlled
21 substances.

22 **Q.** And has that been the regulatory requirement throughout
23 your tenure at DEA?

24 **A.** Yes.

25 **Q.** And why do you believe that the obligation is on a

1 registrant to design and operate a system rather than on the
2 DEA to direct it?

3 **A.** Because that's what the -- the regulation says and we
4 follow the regulation. That's also -- I believe in one of
5 the letters I -- we wrote, I think it's the December 2007
6 letter where we explained why that was -- that was
7 important. It's the registrant's obligation. It's not
8 DEA's obligation.

9 **Q.** And why is that?

10 **A.** Because only the registrant knows or can develop a
11 system that conforms to their business plan, to their
12 customer base. DEA can't do that. DEA doesn't know what
13 their customer base is. Doesn't know what their business
14 plan is. Doesn't know how they process orders. Only the
15 registrant could do that.

16 And so, we give them that flexibility so they could,
17 they, make that determination of what Suspicious Order
18 Monitoring Program works within the confines of their
19 business.

20 **Q.** All right. We can take that down.

21 Mr. Rannazzisi, and I forget who it was, but I believe
22 you were shown yesterday a report that criticized DEA's
23 guidance to registrants. Do you recall discussions about
24 whether DEA's guidance was sufficient?

25 **A.** Yes, I do.

1 Q. And do you agree with that criticism?

2 A. No, I do not.

3 Q. Are you aware whether others in DEA believed that the
4 agency's guidance was appropriate?

5 MR. SCHMIDT: Objection, hearsay, foundation.

6 THE COURT: Sustained.

7 BY MS. SINGER:

8 Q. Can you remind us who Gary Boggs is?

9 A. Gary Boggs was my Executive Assistant from 2006 to the
10 time he left, which I believe was around 2011 or '12.

11 Q. And what does he do now, if you know?

12 A. He was working at McKesson, but I believe he's retired
13 now.

14 MS. SINGER: Let's do P-28214, please.

15 May I approach, Your Honor? I think this will be the
16 last time.

17 BY MS. SINGER:

18 Q. Mr. Rannazzisi, have you seen this document before,
19 P-28214?

20 A. Yes, I've read this before.

21 Q. And I'd like to direct your attention to the third page
22 of the document.

23 MR. SCHMIDT: And, Your Honor, in the interest of
24 time, I think what we're about to try to do is introduce a
25 hearsay statement from a newspaper article. We object. And

1 the setup is it's purporting to quote Gary Boggs without Mr.
2 Boggs being here to testify.

3 THE COURT: Well, what are you using this for?

4 MS. SINGER: Your Honor, what I want to ask is
5 whether Mr. Rannazzisi is aware that this statement was made
6 while Mr. Boggs was working under his supervision at DEA and
7 whether he agrees with the statement in the newspaper
8 article. I believe that, again, this is his employee during
9 his tenure.

10 THE COURT: Okay. I'll let you ask him that.

11 MR. SCHMIDT: And, Your Honor, just reading him
12 the statement and asking him, that's literal hearsay,
13 reading that into the record.

14 THE COURT: That's right. Don't read him the
15 statement. You can ask him about it.

16 MS. SINGER: Okay.

17 BY MS. SINGER:

18 Q. And, Mr. Rannazzisi, do you recall Mr. Boggs making a
19 statement about DEA's -- about -- about industry's reaction
20 or criticism of DEA's guidance?

21 MR. SCHMIDT: And that I'll object to as hearsay.

22 THE COURT: Let me see. Well, I'll overrule the
23 objection to that question. The question was did he recall
24 Mr. Boggs making the statement about the industry's reaction
25 or criticism of DEA's guidance. If he can answer that

1 without getting into hearsay, the hearsay would be in the
2 statement itself. So, I'll overrule that objection. Go
3 ahead.

4 THE WITNESS: I'm sorry, ma'am. Could you repeat
5 the question?

6 MS. SINGER: Yes.

7 BY MS. SINGER:

8 **Q.** Do you recall Mr. Boggs making a statement while he was
9 under your employ or under your supervision at DEA regarding
10 industry's response -- industry's criticism of DEA's
11 guidance?

12 **A.** Mr. Boggs was my -- in addition to my exec, he also was
13 the person who did the media interviews for my office. So,
14 Mr. Boggs made a lot of statements in the media regarding
15 certain aspects of my office. I know Mr. Boggs' statements
16 were always -- always conformed to what the office policies
17 and what the DEA policies and procedures were at the time he
18 was there, the time I was there.

19 I can't give you the exact specific statement that he
20 made in this -- in this -- in this document because I didn't
21 look at it and I recall reading it, but Mr. Boggs has made
22 so many statements, I just -- I can't recall the specific
23 statement he made in this document.

24 **Q.** And was he -- were his statements to the press made
25 under your supervision?

1 **A.** Yes, they were.

2 **Q.** And were they within the scope of his authority?

3 **A.** It was the scope of his authority, which was my
4 authority, to make statements to the press.

5 **Q.** And did his statements reflect your direction and the
6 policy of DEA under your leadership?

7 **A.** Always.

8 MS. SINGER: So, Your Honor, I'd like to ask Mr.
9 Rannazzisi to reflect -- to testify as to whether this
10 statement reflects his own state of mind and his guidance
11 and belief when he was at DEA. Mr. Schmidt didn't even need
12 me to finish before he stood up, but I do not believe that's
13 hearsay because it's both within the scope of his authority.

14 THE COURT: Mr. Schmidt?

15 MR. SCHMIDT: There's no hearsay exception that
16 says if someone said something while they were working as
17 your colleague and, purportedly, he's now testifying as to
18 Mr. Boggs' state of mind in everything he said, every single
19 thing he said. That's one problem in terms of foundation.

20 And the second problem is that doesn't make it hearsay.
21 We wouldn't need the government records exception if you
22 could just say a witness was speaking while he was a
23 government official and, therefore, hearsay.

24 If they want to -- they can't bring it in under the
25 government exception, so they're trying to come up with some

1 other argument for it, but there's no way around hearsay
2 like that.

3 If they want to just say to him do you agree with this
4 point, that's fine, but the very clear point they're trying
5 to make here is Mr. Boggs said this in a few lines in a
6 newspaper article. He went to work for McKesson.
7 Therefore, got ya, McKesson. That's -- that's pure hearsay,
8 Your Honor.

9 THE COURT: Ms. Wicht?

10 MS. WICHT: Your Honor, I would add to that a
11 relevance objection. I -- Ms. Singer says this goes to, I
12 think, either Mr. Rannazzisi's or Mr. Boggs' state of mind
13 and I don't -- I don't know what that's relevant to in this
14 litigation.

15 THE COURT: Well, Ms. Singer, you can tell him
16 what the statement Mr. Boggs made was and ask him if he
17 agrees with it, but that's all.

18 MS. SINGER: And that's all I intended to do, Your
19 Honor.

20 THE COURT: Okay.

21 MS. SINGER: All right.

22 BY MS. SINGER:

23 Q. Mr. Rannazzisi, reading the quote from Mr. Boggs, the
24 notion put out by HDMA -- and I think you've said you're
25 familiar with HDMA. Are you?

1 **A.** Yes. They're now HDMA, but same organization.

2 **Q.** So, the notion put out by HDMA that somehow or another
3 the DEA is not providing essential information to them is
4 simply not accurate, says Boggs. It's a smoke screen. It's
5 a step out of desperation. Do you agree with that
6 statement?

7 **A.** Yes, I do.

8 **Q.** Mr. Rannazzisi, during Mr. Nicholas's questioning this
9 morning he showed you a page from DEA's website referring to
10 a presentation that was made by Mr. Zimmerman and I think
11 that Mr. Mapes was also at. Do you recall that questioning?

12 **A.** Yes.

13 **Q.** All right. I'd like to cull up the presentation
14 itself, which is already in evidence. So, Mr. Rannazzisi,
15 showing you DEF-WV-00001, I'd like to turn to Slide 12. I'm
16 sorry. Slide 7. And do you recall Mr. Nicholas asking you
17 about retail chain pharmacies being exempted? Do you
18 remember that question?

19 **A.** Yes.

20 **Q.** And on the presentation itself, what does that bullet
21 point refer down from?

22 MR. NICHOLAS: Well, I'll object, Your Honor. Mr.
23 Rannazzisi wasn't -- didn't attend the presentation, so
24 there's no foundation for this.

25 MS. SINGER: Your Honor, if I may, Mr. Nicholas

1 asked Mr. Rannazzisi to interpret DEA language about a
2 presentation and particularly its exemption of retail
3 pharmacies and asked Mr. Rannazzisi if that was accurate.
4 Mr. Nicholas didn't show him the presentation itself, which
5 limits the meaning of that statement, and I think Mr.
6 Rannazzisi should be entitled to explain the contact.

7 THE COURT: Yeah. You opened the door to this,
8 didn't you, Mr. Nicholas?

9 MR. NICHOLAS: I didn't think so, Your Honor,
10 because all I showed him was the DEA website description,
11 which is all I wanted him to comment on, the fact that it
12 was presented by the DEA, not so much all the -- you know,
13 the slide presentation. So, I would have thought not.
14 That's why I objected.

15 THE COURT: Ms. Wicht?

16 MS. WICHT: Well, I would just add to that that I
17 think the only way -- if what he's being asked to do is
18 explain the context, the only thing he can offer is to read
19 the document that's in front of him since he wasn't there.
20 I'm not sure that gives him the foundation to explain the
21 context. So, we would join the objection.

22 THE COURT: Well, I'm going to allow it. I think
23 it's properly responsive to the questions that Mr. Nicholas
24 asked and I'll allow you to go ahead, Ms. Singer.

25 MS. SINGER: And I promise to be brief on this,

1 Your Honor. Just a single point.

2 BY MS. SINGER:

3 **Q.** Mr. Rannazzisi, do you understand or can you -- can you
4 -- can you explain the context in which the retail chain
5 pharmacies are exempted, appears in this presentation?

6 **A.** Yes. When a distributor begins a business relationship
7 with a pharmacy, be it a retail pharmacy, any retail
8 pharmacy, they have to do certain things to ensure that that
9 retail pharmacy is going to be operating in a manner that's
10 consistent with law. So, they will do certain things. And
11 this is mostly on the independent side because the
12 independents are just that, they're independent pharmacies.
13 There's a Pharmacist in Charge and an owner. And they do
14 background. And they do certain things to make sure that
15 that pharmacy is going to be operating within the confines
16 of the law.

17 With a chain drugstore, it's different. The chain
18 drugstore is a corporation, generally a major corporation,
19 and they have Central Offices that deal with the exact same
20 thing for their pharmacy.

21 So, if a pharmacy, a brand new chain drugstore opens up
22 and it's a new pharmacy within the chain, they'll look to
23 the Central Office to ensure that all of those things have
24 been done. They won't do the -- they won't do what they do
25 with the independent.

1 That doesn't mean they won't do due diligence after the
2 pharmacy is opened. It just means on that initial pharmacy
3 opening, before it's open, before they accept that pharmacy
4 as a customer, they will exempt certain obligation --
5 certain procedures that they would do normally in the
6 independent pharmacy because it's a centralized chain;

7 So, this only involves new business relationships with
8 that particular pharmacy within that chain. It doesn't
9 involve due diligence after the fact.

10 Once the chain is set up, once it's in operation, it
11 goes through the same due diligence procedures that
12 everybody else does. This is just specifically for that
13 initial business relationship where they have to establish
14 that the pharmacy has the, you know, proper licensure,
15 proper registrations, and also the appropriate review of the
16 laws.

17 THE COURT: Ms. Wicht?

18 MS. WICHT: Your Honor, I would simply object that
19 if that lengthy answer was intended to be reciting what was
20 conveyed at the meeting, there's absolutely no foundation
21 for it.

22 THE COURT: Well, the question was having him
23 explain why retail chain pharmacies are exempted, wasn't it,
24 Ms. Singer?

25 MS. SINGER: That's right, Your Honor.

1 THE COURT: And I think his answer was responsive
2 to that question and I think it was a proper question, so I
3 will overrule the objection.

4 BY MS. SINGER:

5 Q. All right. So, Mr. Rannazzisi, we spent a long time
6 yesterday looking at the DEA dispensing controlled
7 substances for the treatment of pain. Can we cull up,
8 please, DEF-WV-03076?

9 MR. SCHMIDT: May we get a copy just to avoid the
10 concern Mr. Ackerman mentioned?

11 MS. SINGER: It is a defense exhibit, Mr. Schmidt,
12 that you questioned on yesterday. It's that one.

13 MR. SCHMIDT: Yeah. I'm just trying to avoid
14 having to go through our boxes to find it.

15 MS. SINGER: Okay. I don't have a -- an extra copy
16 since it was the defendants', but I'm happy to give you time
17 if you need time to pull it up.

18 MR. SCHMIDT: I don't want to slow you down, so go
19 ahead.

20 MS. SINGER: Thank you.

21 BY MS. SINGER:

22 Q. All right. Mr. Rannazzisi, let's look at Page 5. We
23 will pull it up on the screen. So, do you recall being
24 asked -- I think Mr. Schmidt directed you to the heading.

25 MS. SINGER: Up a little bit, Gina. Thank you.

1 The heading on that column.

2 BY MS. SINGER:

3 Q. The number of physicians who prescribe controlled
4 substances in violation of the CSA is extremely small and
5 there is no DEA crackdown of physicians. Do you remember
6 being asked about that headline?

7 A. Yes.

8 Q. And then Mr. Schmidt drew you to the italicized
9 language. Do you remember that conversation?

10 A. Yes.

11 Q. Okay. And those -- those are both statements of the
12 DEA, correct?

13 A. Yes, they are.

14 Q. Okay. But there was another paragraph that you didn't
15 cover yesterday and I want to look at the last paragraph and
16 ask you to read from the middle of that paragraph or you can
17 read the whole paragraph so there's no question about what
18 the DEA is saying. Can you start at DEA always had?

19 A. DEA always had, and continues to have, a legal
20 obligation to investigate the extremely small fraction of
21 physicians who use their DEA registration to commit criminal
22 acts or otherwise violate the CSA.

23 DEA takes this obligation seriously because even just
24 one physician who uses his/her DEA registration for criminal
25 purposes can cause enormous harm. In the words of one

1 commenter: "It takes only a few untrained or unscrupulous
2 physicians to create a large -- large pockets of addicts."

3 **Q.** Stop there, Mr. Rannazzisi. That statement is a
4 statement of the DEA, as well, correct?

5 **A.** Yes.

6 **Q.** And do you believe that statement provides context for
7 the statements that counsel showed you earlier?

8 **A.** Yes.

9 MS. SINGER: I have nothing further, Your Honor.

10 THE COURT: Is there any re-cross?

11 MR. SCHMIDT: Yes, Your Honor. May I proceed?

12 Mr. Reynolds, are you ready to proceed?

13 **RE-CROSS EXAMINATION**

14 **BY MR. SCHMIDT:**

15 **Q.** Mr. Rannazzisi, I'll try to just go through a few of
16 the topics that you touched on with counsel just now and
17 let's start with P-16.

18 MR. SCHMIDT: Can we put this up on the screen,
19 please?

20 **BY MR. SCHMIDT:**

21 **Q.** And do you recognize that this is that Order to Show
22 Cause documentation you were asked about a few minutes ago?

23 **A.** Yes.

24 **Q.** And if we go to Page 139 of this document, do you see
25 it has your proposed testimony that was just read into the

1 record? Do you remember that?

2 **A.** Yes.

3 **Q.** And that's what you thought was important as testimony
4 in this case, correct?

5 **A.** This is what I was going to testify to, not whether it
6 was important. It was what I was supposed to testify to.

7 **Q.** And what you were going to testify to in Item 2 was
8 that you asked a McKesson representatives if they could give
9 you any reason why DEA should not revoke McKesson's
10 registration, and the McKesson officials did not explain why
11 their large distributions to pharmacies under suspicious
12 circumstances. It looks like it's an incomplete clause, but
13 do you see that language?

14 **A.** Yes.

15 **Q.** It never says in there or in any other part of this
16 that they looked at you and smiled and said you got us, does
17 it?

18 **A.** Well --

19 **Q.** Does it say that, sir?

20 **A.** It does not say that, no.

21 **Q.** Thank you. Let's go to P-13, the 2017 Settlement
22 Agreement, at Page 2, just to orient us. You've never seen
23 this document before. Plaintiffs' lawyer showed it to you
24 after you left the DEA, correct?

25 **A.** That's right.

1 **Q.** Let's go to Page 3, the language you were asked about,
2 the acceptance of responsibility, and what I would like to
3 do is -- actually, Page 4 of the document, that little
4 number at the bottom, and if you cull up that paragraph that
5 you were asked about and five lines from the bottom the word
6 "it" appears halfway down the line. It did not identify or
7 report to DEA certain orders placed by certain pharmacies
8 and just -- let's just go up to pharmacies. Do you see that
9 language?

10 **A.** Yes.

11 **Q.** Do you know if any of those orders or pharmacies are in
12 Huntington-Cabell?

13 **A.** No.

14 **Q.** There's no language in there about failing to block,
15 correct?

16 **A.** No.

17 **Q.** And you don't know whether these certain orders to
18 certain pharmacies were blocked or not, correct?

19 **A.** I do not know. It's not in here.

20 **Q.** Let's go to Page 15 of the document, please. And could
21 you just tell us the latest data you see there of this
22 agreement?

23 **A.** January 17th of 2017.

24 **Q.** Okay. Let's cull up DEF-WV-1597, please. Do you
25 remember talking about this report and being asked about it

1 again on re-direct?

2 **A.** Yes.

3 **Q.** Let's go to Page 36 of the report, please, and having
4 in mind that January 2017 date, we'll cull up the middle
5 paragraph. Just over halfway down, one diversion program
6 manager. Do you see that language?

7 **A.** Yes.

8 **Q.** Describe the SORS database as a "joke" noting that DEA
9 Field Division staff did not receive access to the SORS
10 database until 2017. The SORS database is the DEA
11 Suspicious Order Reporting System database, correct?

12 **A.** Yes.

13 **Q.** Diversion from the medical cabinet. Do you remember
14 being asked questions about that on re-direct? And,
15 specifically, the statement you made in the New Mexico
16 presentation that the most frequent method of obtaining a
17 pharmaceutical controlled substance for non-medical use was
18 friends and family for free? Do you remember being asked
19 those questions?

20 **A.** Yes.

21 **Q.** And you said that that was based on a survey, right?

22 **A.** It was based on a national survey.

23 **Q.** And that national survey came from our Centers for
24 Disease Control, correct?

25 **A.** No. The national survey is done by the University, if

1 I'm not mistaken.

2 **Q.** And you didn't know that there was CDC data discussed
3 within the DEA supporting your slide?

4 **A.** The national survey, which is what's the basis of that,
5 is a university survey.

6 **Q.** Did you know --

7 **A.** No, I didn't.

8 **Q.** -- there was Centers for Disease Control data discussed
9 within the DEA that was consistent with your slide?

10 **A.** No, I didn't know that.

11 **Q.** Do you understand, and I think you explained that the
12 position you were stating was not your view, but the
13 official view of the DEA, correct?

14 **A.** That's correct.

15 **Q.** And how many times did you say you gave that
16 presentation?

17 **A.** A lot. I can't give you the number. I'd venture to
18 say 50, 60, 70 times during my tenure.

19 **Q.** And you also made that presentation to the United
20 States public before Congress, correct?

21 **A.** Yes.

22 **Q.** How many other times other than those 50 or 60 times in
23 those presentations to the United States public before
24 Congress did you say things while you were at the DEA that
25 you didn't believe in?

1 **A.** Again --

2 **Q.** How many times, sir?

3 **A.** I -- I'm portraying -- I'm giving the public and
4 Congress what the position of the United States Government
5 is and you know that. That's what the obligation of the
6 witness is, to -- to bring forward the information that the
7 United States Government wants Congress to have, not what
8 Joe Rannazzisi wants it to have.

9 If they were to ask me in my personal capacity, in my
10 personal capacity, what my feelings were on that particular
11 issue, I would have had to tell them, but since I was a
12 government witness, I have to give the information that the
13 government wants me to give.

14 **Q.** You were the senior most official in charge of
15 diversion at the DEA, true?

16 **A.** That's absolutely correct.

17 **Q.** So, come back to my question. Do you know how many
18 times before the public, before the United States Congress
19 or Senate, you said things that were the government position
20 that you didn't believe in?

21 **A.** No. I always present the government's position, which
22 is my requirement as a government official.

23 **Q.** And can you answer my question now, sir?

24 **A.** I said -- I did. I don't know.

25 **Q.** How many times did it happen, sir?

1 **A.** I don't know.

2 **Q.** Okay. Do you remember being asked about testimony
3 regarding prescriber registration and you were read some of
4 the exchanges you and I had from the Ohio deposition? Do
5 you recall that?

6 **A.** Yes.

7 **Q.** Let's cull that up. It's the -- I'm sorry. I'm going
8 to need a date. July 16th, 2020, Page 128.

9 And do you remember being asked on re-direct about the
10 testimony up to Line 11 where you stopped and you said so we
11 stopped doing it? Do you see that?

12 **A.** Yes.

13 **Q.** Okay. Let's keep reading.

14 MR. SCHMIDT: Can we scroll down, please, and
15 let's just get the next two questions and answers. We're
16 missing part of the second answer. We need the full second
17 answer, please.

18 BY MR. SCHMIDT:

19 **Q.** Do you see I went on to ask you did you run background
20 checks at any point in time on every single prescriber who
21 was applying for a license from DEA for a registration? And
22 you say I can't say every single -- most of them, yeah.
23 They were run out of the local offices.

24 Did I read that correctly?

25 **A.** Yes.

1 **Q.** And I said did you check prescriber criminal records
2 when they applied for re-registration on every prescriber at
3 any point in time?

4 Do you see that?

5 **A.** Yes.

6 **Q.** And you said that, I don't recall. I just don't recall
7 that.

8 Do you see that?

9 **A.** Yes.

10 **Q.** All right. Let's go on to the next document,
11 DEF-WV-3076. This is that 2006 policy statement. I think
12 it was the very last document you were asked about on
13 re-direct. Do you recall that?

14 **A.** Yes.

15 **Q.** And I want to go back to the language you were asked
16 about which appears on the bottom of Page 5 and the bottom
17 -- it's the right corner, that bottom paragraph. You were
18 asked to read the first sentence.

19 DEA always had, and continues to have, a legal
20 obligation to investigate the extremely small fraction of
21 physicians who use their DEA registration to commit criminal
22 acts or otherwise violate the Controlled Substances Act.

23 Do you see that?

24 **A.** Yes.

25 **Q.** Is that a true statement that the DEA has a legal

1 obligation to investigate the extremely small fraction of
2 physicians who violate the CSA?

3 **A.** Yes, we do have. That's what our charge is under Title
4 21.

5 **Q.** Is that something that the public and the healthcare
6 system can rely on, that the DEA will faithfully execute
7 their legal obligation to investigate doctors who violate
8 the CSA?

9 **A.** Yes.

10 **Q.** It goes on to say the DEA takes this obligation
11 seriously. Is that true, that DEA takes its obligation to
12 the public and the healthcare community to act against the,
13 quote, "extremely small fraction of physicians who violate
14 the CSA"?

15 **A.** Yes.

16 **Q.** And then just to round out the language that you were
17 read, I think you stopped after the quotation mark. Do you
18 see that quotation mark?

19 **A.** Yes.

20 **Q.** I want to just read the rest. But DEA takes just as
21 seriously its obligation to ensure that there is no
22 interference with the dispensing of controlled -- and we can
23 go to the next page -- substances to the American public in
24 accordance with the sound medical judgment of their
25 physicians.

1 It would be a disservice to many patients if
2 exaggerated statements regarding the likelihood of a DEA
3 investigation resulted in physicians mistakenly concluding
4 that they must scale back their patient's use of controlled
5 substances to levels below that which is medically
6 appropriate.

7 Is that something you believed when you were at the
8 DEA?

9 **A.** I believe that legitimate patients should be treated
10 appropriately.

11 **Q.** And you believed that it was an extremely small
12 fraction of doctors who were acting illegitimately, correct?

13 **A.** Yes.

14 **Q.** Last topic, sir. DEF-WV-2578. This is the *Masters*
15 decision that you were shown. And let's go to the language
16 you were shown on Page 59, please, in the middle column.
17 You were shown right at the end of that carryover paragraph
18 the sentence that begins "thus".

19 MR. SCHMIDT: Right above where you are, Mr.
20 Reynolds.

21 BY MR. SCHMIDT:

22 **Q.** Do you see where this sentence says, thus, it argues
23 that the agency was required to announce the positions taken
24 in the letter by engaging in notice and comment rulemaking.
25 Respondent's argument is not well taken.

1 Do you see that language?

2 **A.** Yes.

3 **Q.** And you were asked about that on your re-direct
4 examination, correct?

5 **A.** Yes.

6 **Q.** Let's go to how that reasoning was explained. Can we
7 go to Page 60? Upper right paragraph, please. It picks up
8 on that idea of notice and comment rulemaking by saying the
9 Supreme Court, however, long ago rejected the contention
10 that an agency must announce all rules it adopts only
11 through notice and comment rulemaking. And it actually has
12 legal citations from the United States Supreme Court.

13 Do you see that?

14 **A.** Yes.

15 **Q.** And then the source it cites after that as to how the
16 due diligence rule was announced is the *Southwood* decision,
17 correct?

18 **A.** Yes.

19 MR. SCHMIDT: Thank you, sir. That's all I have.

20 THE COURT: Do you have anything else, Ms. Wicht?

21 MS. WICHT: I don't have any further questions.

22 Thank you, Your Honor.

23 And thank you, Mr. Rannazzisi.

24 MR. NICHOLAS: I have no questions.

25 Thank you, Mr. Rannazzisi.

1 THE COURT: Now, may Mr. Rannazzisi be excused?

2 MS. SINGER: I think he has more than done his
3 time, Your Honor. Yes.

4 MR. SCHMIDT: Thank you, Mr. Rannazzisi.

5 THE COURT: You're free to go, Mr. Rannazzisi.
6 Thank you, sir, very much, and good luck to you.

7 THE WITNESS: Thank you very much. Thank you,
8 SIR, very much. Have a good day.

9 THE COURT: Thank you, sir.

10 MR. SCHMIDT: Thank you, sir.

11 MS. WICHT: Thank you, sir. Take care.

12 THE COURT: Can we start another witness before
13 noon?

14 MR. ACKERMAN: Yes, Your Honor, but I don't think
15 we need to -- I think we need to go get the witness.

16 MR. FARRELL: Yes, Your Honor. Can you give us
17 ten seconds to --

18 THE COURT: Yeah. Sure.

19 MR. WESTFALL: Your Honor, since Mr. Rannazzisi is
20 finished with his testimony, may I be excused?

21 THE COURT: I see no reason whatsoever why you
22 shouldn't be excused. Thank you, sir, very much.

23 MR. WESTFALL: Thank you, Your Honor.

24 MS. KEARSE: Good morning, Your Honor.

25 THE COURT: Good morning.

1 MS. KEARSE: My witness just stepped in the -- I'm
2 sorry.

3 (Pause)

4 MS. KEARSE: Your Honor, the plaintiffs would like
5 to call Dr. Gordon Smith to the stand.

6 THE COURT: All right.

7 COURTROOM DEPUTY CLERK: Sir, would you please
8 state your full name?

9 THE WITNESS: Gordon Stephen Smith.

10 COURTROOM DEPUTY CLERK: Thank you. Please raise
11 your right hand.

12 **DR. GORDON STEPHEN SMITH, PLAINTIFF WITNESS, SWORN**

13 COURTROOM DEPUTY CLERK: Thank you. Please take a
14 seat.

15 THE COURT: Good morning, sir.

16 THE WITNESS: Good morning.

17 MS. KEARSE: Okay. I can still say good morning.

18 THE WITNESS: Yes.

19 **DIRECT EXAMINATION**

20 **BY MS. KEARSE:**

21 **Q.** Good morning, Dr. Smith. Can you please introduce
22 yourself to the Court?

23 **A.** I'm Gordon Smith. I'm a public health epidemiologist
24 at the West Virginia University School of Public Health in
25 Morgantown.

1 **Q.** And as -- and the Department of Epidemiology, is that
2 safe to say you are an epidemiologist?

3 **A.** Yes. I am an endowed Professor of Epidemiology at the
4 West Virginia School of Public Health and my specialty is
5 epidemiology, public health epidemiology.

6 **Q.** Can you tell the Court what is epidemiology? You are
7 the first epidemiologist up here so --

8 **A.** Epidemiology has a very broad thing, but we're really
9 -- the best definition to separate it out is to look at the
10 difference between treating an individual patient as a
11 clinical physician as against someone who treats and studies
12 the community. Studies the disease transmission in the
13 community and risk factors for people getting certain
14 conditions, be it an injury, or a disease, and then we look
15 at how to apply that information in the area of prevention
16 in public health.

17 **Q.** Can you give the Court just an example of what would be
18 considered the study of epidemiology of a community or a
19 population?

20 **A.** Well, exactly. I think the best example to me is we
21 are always teaching our students is that of the cholera
22 outbreak in London in the John Snow Pub.

23 So, it was basically different areas of London and --

24 COURT REPORTER: Sir, you're going to have to slow
25 way down for me, please, okay? Way down.

1 THE WITNESS: Thank you.

2 COURT REPORTER: Thank you. Sorry.

3 MS. KEARSE: I warned him.

4 THE WITNESS: Thank you. There were different
5 areas of London that were served by different water supply
6 companies and he put a little map together and studied and
7 showed that all of the cases, almost all the cases were
8 coming from one particular area served by one particular
9 pump.

10 And the classic prevention -- so, he studied it. He
11 said everybody came from that area. So, what did he do? He
12 took the pump handle off and then people couldn't be
13 drinking the contaminated water. So, that's a good classic
14 example of a live public health problem.

15 And, in the same way, we look at how factors increase
16 the risk of something happening. For example, the risk of
17 dying of a drug overdose, what are the factors related to
18 that risk and what kind of things were you consuming, such
19 as prescription drugs or whatever.

20 BY MS. KEARSE:

21 **Q.** And, Doctor, you have a specialty in epidemiology then
22 as it applies and relates to drug overdoses?

23 **A.** Yes, I do. Within epidemiology, like any field, there
24 are a variety of different specialties and people specialize
25 in different areas. My application -- my specialty area is

1 in the area of data, looking at the public health data,
2 looking at causes of death, looking at factors responsible
3 for causes of death, and various factors that might increase
4 that death with a specialty on the area of injury, poisoning
5 and drug overdoses.

6 I spent my entire career working in the area of
7 injuries and poisonings and poisonings and drug overdoses is
8 a subsection of the injury, broad injury.

9 **Q.** So, the study of injury mortality?

10 **A.** Injury mortality, yes.

11 **Q.** And, Doctor, have you had -- do you have experience in
12 drug classification and coding systems that assist
13 epidemiologists in their research?

14 **A.** Yes. That's been an area where I've worked a lot on
15 and, in fact, I was responsible for part of an international
16 group for the World Health Organization where we met
17 regularly and we developed the codes for the International
18 Disease Classification-10 for injuries and poisonings,
19 including drug overdoses.

20 And, in fact, one of the various important parts of
21 this revision is that you can now separate out prescription
22 drugs from nonprescription drugs, which you couldn't do in
23 the old disease classification codes. And all of the deaths
24 in the U. S., including here in West Virginia, and in Cabell
25 County, are all from 1979 on -- onwards have all been

1 classified in ICD-10. And I was actually part of the group
2 that wrote the codes to classify the drug overdose deaths.

3 **Q.** Doctor, do you hold other academic appointments?

4 **A.** Yes, I do. I am an assistant professor -- sorry. I'm
5 a Professor of Emergency Medicine at WVU. I collaborate
6 with them on some projects with residents and mainly
7 instruction.

8 I am also an adjunct professor at the University of
9 Maryland School of Medicine. And I also have an affiliate
10 status with the Harvard -- with the Johns Hopkins School of
11 Public Health or is now called the Bloomberg School of
12 Public Health because I've collaborated with people on a
13 number of projects there and I'm on their Advisory Board for
14 their Occupational Injury Training Program, which was
15 something that I developed myself many years ago.

16 **Q.** Doctor, how long have you been in research and
17 academia?

18 **A.** Well over 30 years. Probably 35 years or more.

19 **Q.** Dr. Smith, have you worked on -- provided some slides
20 that would help go over these qualifications and other
21 things for your testimony today?

22 **A.** Yes. Yes, because I wanted to be -- as an
23 epidemiologist, we're really into accuracy. We really like
24 to have -- know that the numbers we give out are the real
25 numbers and you'll see that as I go through with this.

1 And so, I don't always carry all my numbers in my head.
2 While my head is a little computer, it doesn't always give
3 me the right answer. And so, I like to have the --

4 **Q.** I think we'll start with the slides, okay?

5 **A.** The slides.

6 MS. KEARSE: Your Honor, may I approach?

7 MS. WU: Your Honor, we've been through this with
8 a few other witnesses and we don't object to the use of
9 demonstratives with the witness but, of course, would ask
10 that counsel lay the proper foundation for the
11 demonstratives before prompting the witness with them.

12 THE COURT: All right. You can do that, Ms.
13 Kearse.

14 MS. KEARSE: Yes, Your Honor. These are not
15 single slides, but counsel has copies.

16 Your Honor, I would also like to just present just as a
17 court exhibit, not for evidence, just a copy of Dr. Gordon's
18 CV. Would that --

19 THE COURT: Yes.

20 MS. KEARSE: And we'll go through these
21 qualifications quickly so we can --

22 BY MS. KEARSE:

23 **Q.** Doctor, there's a copy of your CV. Quickly, I want to
24 go over some of these. I don't want to repeat what we've
25 gone over already, but I'm showing you what is Demo 233 and

1 also handed the Court and Dr. Smith a copy of your CV that
2 we can highlight there but, obviously, to save time, I won't
3 go over everything with that.

4 But, Doctor, you've talked about you're an
5 epidemiologist at WVU and other things there, too. Can you
6 go through a little bit more of your background, educational
7 background, that we haven't discussed?

8 **A.** Okay. My first educational background was a -- my
9 medical degree from Otago University in New Zealand. And in
10 case you're wondering where my funny accent's from, I'm from
11 New Zealand and that's where I was born and brought up in a
12 small rural town, I might add, of about two and a half
13 thousand population.

14 **Q.** And that's where you got your undergraduate degree?

15 **A.** Yeah. My undergraduate degree was at Otago University
16 in Dunedin and we have a combined undergraduate. It's a
17 six-year medical training program, which is a combined
18 undergraduate at -- in sort of general sciences and
19 medicine.

20 And so, my technical degree is M.B., Ch.B., but it's a
21 direct equivalent to the medical degree here. And just as a
22 word of note, our medical school has some of the top schools
23 of any of the international medical schools in the country,
24 in the world, and the American equivalency exam.

25 **Q.** Did you study medical training there, as well?

1 **A.** Yes.

2 **Q.** And are you a permanent resident now of the United
3 States?

4 **A.** Yes, I am a permanent resident of the United States. I
5 came to the States in 1980 to do my Masters of Public Health
6 at the Harvard School of Public Health. And then, while I
7 was here, I realized the incredible training opportunities
8 in the States for public health and epidemiology.

9 So, I was accepted into a training program at the
10 Centers for Disease Control, but then I deferred for a year
11 to do a project because my wife had another -- another -- so
12 I did research at the Harvard School of Public Health. And
13 then I joined the Centers for Disease Control what they call
14 an Epidemic Intelligence Officer. And a very fancy-sounding
15 name, but essentially it's a training for the -- we're the
16 people that go out and track Ebola and you see it in the
17 movies probably and you read about it occasionally. And
18 it's exactly the same people that come out to help West
19 Virginia on particular problems, which we can talk about a
20 little later.

21 And then I went on and did my preventive medicine
22 residency at the Centers for Disease Control and, in that, I
23 might add that I did my -- most of my time in the -- in the
24 State of Colorado working very much in rural problems and
25 outbreaks of pertussis in tiny little towns.

1 And then I went to Nigeria as a consultant for CDC on
2 Guinea Worm Disease or Dracunculiasis --

3 COURT REPORTER: I'm sorry. What was that?

4 MS. KEARSE: Yes. That's okay. I was going to
5 stop you.

6 THE WITNESS: Great. Slow me down. Good. Thank
7 you.

8 BY MS. KEARSE:

9 **Q.** So, Doctor, what we'll do is we'll go through education
10 and then we'll go through your work and --

11 **A.** Okay, good. That sounds good.

12 And so, my education, I got my Master's in Public
13 Health at Harvard and --

14 **Q.** Wait.

15 COURT REPORTER: I'm sorry.

16 MS. KEARSE: Yes. That's okay. We'll slow it
17 way, way down.

18 THE WITNESS: Masters in Public Health at Harvard
19 and, as you can see, I get excited because I really enjoy my
20 career.

21 BY MS. KEARSE:

22 **Q.** So, let me ask you this, Doctor. With your public
23 health and -- your education in public health, can you tell
24 the Court exactly what does the study of public health
25 involve?

1 **A.** The study of public health is involved in this broader
2 aspect of the public -- looking at prevention and management
3 of disease in the community as a whole and, while I said
4 epidemiology studies the community and diseases in the
5 community, public health is part of epidemiology.

6 Epidemiology is generally considered to be part of public
7 health, but it's the application of prevention strategies to
8 the community so that we treat the whole community with a
9 public health intervention, such as taking the handle off
10 the pump. That didn't make any difference to one individual
11 patient, but it stopped them from getting disease.

12 **Q.** Thank you, Doctor. And I think you went over, it went
13 very fast, some of your -- what you've been involved in
14 prior to becoming -- coming to West Virginia. But, just
15 briefly, you were also, I think you mentioned, a principal
16 research scientist with Liberty Mutual. I don't know if you
17 said that or not, but I know that you were going quickly, so
18 I want to make sure that --

19 **A.** Yes. I was a Professor of -- Assistant Professor. My
20 first formal academic appointment was an Assistant Professor
21 at Johns Hopkins School of Public Health. And then I did --
22 spent my time there working on injury-related projects,
23 including some poisonings, and some drug work, and substance
24 abuse in general was part of it. I developed a substance
25 abuse training program there.

1 And then I went to work for the Liberty Mutual Research
2 Institute, which is an occupational injury -- studies
3 workplace injuries and how to prevent workplace injuries.
4 Not how to treat them, but how to prevent workplace
5 injuries. And we're affiliated with the Harvard School of
6 Public Health and the causes there.

7 **Q.** Where did you start your public health research?

8 **A.** Actually, I really started my public health research in
9 the Highlands of Papua, New Guinea, of all places. I went
10 there originally as a clinical doctor. And then, the more
11 and more I worked in these remote areas, I realized that
12 medicine was a little bit like sticking your finger in a
13 dyke. You were just plugging up the holes. And that,
14 really, prevention was a much better way to start looking at
15 things.

16 And I was very fortunate to run an epidemiology field
17 station. I didn't know anything about epidemiology when I
18 started in the Highlands of Papua, New Guinea.

19 **Q.** What year was that? What year was that? Just so we
20 can see the history of your involvement.

21 **A.** This was from 1976 to 19 -- 1980. And what I did, what
22 I did there is that we studied the causes of death in these
23 remote rural areas. This was an area of the world where
24 they only discovered it in 1950, as far as the Europeans
25 were concerned. There were local tribes that had been there

1 for a long time and the only way to get in there most of the
2 year was to fly. So, that was a fascinating place.

3 But that's where I learned my field experience and I
4 got addicted to the idea of treating the community rather
5 than treating an individual patient.

6 **Q.** Okay. And, now, we'll fast forward with that. So, I
7 want to -- really just kind of go through some of your
8 additional qualifications.

9 Are you a member of various professional societies
10 related to your work in epidemiology and public health?

11 **A.** Yes, I am. I'm a member of the American College of
12 Epidemiology, International Collaborative Effort on Injury
13 Statistics, the American Public Health Association, and the
14 Society for Drug Dependence.

15 **Q.** And, Doctor, what brought you to West Virginia?

16 **A.** I was a Professor of Epidemiology at University of
17 Maryland just down the road in their Department of
18 Epidemiology and Public Health. And I've been working on
19 and off in West Virginia for a number of years with people
20 and projects.

21 In fact, I was on the Advisory Board of the Injury
22 Research Center at WVU and they have often tried to recruit
23 me to come to West Virginia and, finally, what convinced me
24 was they had given money for an endowed chair and that's
25 really the gold -- that's sort of the pinnacle -- that's a

1 bit like a Supreme Court appointment, Judge. It's the
2 pinnacle of --

3 **Q.** What is an endowed chair? What is it, Doctor?

4 **A.** No, or a federal judge is probably a better way of
5 looking at it.

6 But it sort of -- and this was an incredible
7 opportunity to come and shift gears a bit, deal with what --
8 I couldn't believe the drug problem in West Virginia. And
9 so, I -- I was part of them bringing in senior people from
10 other universities.

11 And you will later on meet Judith Feinberg, another
12 person who was brought in as part of the University's
13 efforts to how can we get better research to understand
14 what's going on and to then lead to prevention of the drug
15 -- the opioid overdose problem here in West Virginia.

16 **Q.** What type of research, just briefly, have you done
17 since -- have you been engaged in since coming to West
18 Virginia in your --

19 **A.** I've been working on a number of projects. I was
20 actually -- one of the very interesting things is we were
21 doing a study of drug involvement, particularly opioids and
22 other drugs in motor vehicle crashes and, to the extent to
23 which they would increase, because I had done a lot of work
24 and other people had showing that alcohol increased the risk
25 of car crashes. And there was no information on the role of

1 drugs and how they might be involved; in particular,
2 opioids, which we know impairs performance.

3 So we had written a grant basically at University of
4 Maryland to collaborate with colleagues here in West
5 Virginia using their Medical Examiner data and also, later
6 on, to try to use the data from another state out -- out on
7 the West Coast.

8 And the idea of that was to look at what is the
9 involvement of drugs in specific injuries and what were the
10 drug levels? And this is part of epidemiology. Some of the
11 work we do, we're not interested in just finding a drug, but
12 what's the involvement? Because we do know that with
13 alcohol the blood concentrations increases; so does the
14 risk. So, we thought the same thing, that if people had
15 more opioids in their system, their risk would go up.

16 **Q.** Okay. And so -- and just quickly, some of the other
17 things we have on the slide, you're involved in multiple
18 projects; is that fair to say, in studying drug overdoses?

19 **A.** Yeah. And, particularly, we got funded from the
20 National Institute of Drug Abuse to study a field study of
21 opioid problems in the eight southern counties in West
22 Virginia.

23 West Virginia has the highest overdose rate in the
24 country, but these have some of the highest overdose. And,
25 particularly, we were interested there in the problem of

1 rural opioid problems.

2 We'd also thought of studying in this area here, but --
3 and including Cabell County when we first started talking,
4 but the people at Huntington, at Marshall University, were
5 also interested in applying for the same grant. So, we
6 concentrated and that was what we were interested in looking
7 at rural areas.

8 We've got this forensic drug database with the Medical
9 Examiner's Office where we're keeping very -- it's really a
10 research database that looks at the drugs that they had
11 tested in their place and particular use of the
12 concentrations, which is part of my risk.

13 And I'm also working on a big federally funded project
14 to document the impact overall of substance abuse in West
15 Virginia. It's developing policies and plans. And I've
16 been directing the data analysis piece of the data from
17 different sources, including Medicaid, hospital data.

18 **Q.** And you're also doing some work with the Appalachian
19 Regional Commission, is that --

20 **A.** Yes. Actually, the field study that we did down in the
21 eight southern counties, we were then given funding from the
22 Appalachian Regional Commission to develop an intervention
23 project based on what we learned in Mercer County, in
24 Wyoming and McDowell County.

25 And so, we have just got funding in October and we're

1 now making really good progress. And the idea there is to
2 -- how do we outreach to identify the people with drug
3 problems and substance abuse problems, particularly opioids,
4 in these rural areas that are hard to locate and how do we
5 get them into treatment.

6 **Q.** And, Doctor, have you published academic articles?

7 **A.** Yes, I have. I have over 200 articles in various
8 areas. All -- the vast bulk of them related to substance
9 abuse and injury risk, including overdoses.

10 **Q.** And you have chapters in books in regards to
11 epidemiology and injury prevention?

12 **A.** Yes, exactly, all around that and, most recently, since
13 coming here, we've been working on the specific opioid
14 problem here in West Virginia.

15 **Q.** And then also technical reports and publications
16 utilized in the public health community, correct?

17 **A.** Oh, yes. You'll see the weight of my CV. The people
18 joke sometimes you can tell how old someone is by how far
19 down the stairs do they -- their CV flies. So, yes.

20 **Q.** And I'm going to ask you to still slow down and -- to
21 the extent we can.

22 MS. KEARSE: Okay. We're just about there, Your
23 Honor, with the qualifications. Just a couple of more
24 questions.

25 BY MS. KEARSE:

1 **Q.** You're familiar with the medical literature and studies
2 discussing opioids in the State of West Virginia?

3 **A.** Yes. When I first came to West Virginia, I made a big
4 point of looking at all the literature that had been done,
5 all the studies that had been done, and I very much keep up.
6 In fact, I know often many of the researchers that are doing
7 the work here and we often have consultation about it. And
8 I've made a big point of understanding the problem and
9 traveling the state to work with people.

10 **Q.** And do you utilize data in your research into drug
11 overdoses?

12 **A.** Very much so. It's essential to the whole work we've
13 doing, is using the data. And, in particular, I've had a
14 lot of experience, building on my experience in other states
15 and internationally on vital statistics and using Medical
16 Examiner data and that was the basis of a lot of the work
17 that I've done.

18 **Q.** So, you're familiar with both state and national data?

19 **A.** Yes, very much, state and national data.

20 **Q.** And you've reviewed data relevant to opioid-related
21 overdoses in West Virginia; is that correct?

22 **A.** Absolutely. And a key part of it has been looking at
23 the specific county involvement so we actually have data
24 going right down to the county level.

25 **Q.** And that would include the Cabell-Huntington community?

1 **A.** Absolutely includes the Cabell-Huntington community.

2 **Q.** And, Doctor, you were retained by the Cabell-Huntington
3 community to appear as an expert in this matter; is that
4 correct?

5 **A.** That's correct.

6 MS. KEARSE: Your Honor, plaintiffs tender Dr.
7 Gordon Smith to the Court as an expert witness on the
8 subject of epidemiology, drug overdoses and overdose data
9 and trends for the State of West Virginia and Cabell County,
10 in particular.

11 THE COURT: All right. I find that Dr. Smith is,
12 in fact, an expert witness on the subject of epidemiology,
13 drug overdoses and overdose data and trends for the State of
14 West Virginia and Cabell County, in particular.

15 MS. KEARSE: Thank you, Your Honor.

16 THE COURT: So, for what it's worth, you have my
17 imprimatur as a qualified expert, Dr. Smith.

18 THE WITNESS: I'll put that on my CV.

19 BY MS. KEARSE:

20 **Q.** Doctor, I would like to talk a little bit about your
21 assignment in this case and what you were assigned to do.
22 With the vast information you have, we focused your
23 assignment in particular.

24 So, can you tell the Court, what was your particular
25 assignment in this case for the Cabell-Huntington community?

1 **A.** My assignment was to look at the best evidence, the
2 best data I could find on the overdose problem, particularly
3 the opioid overdose problem in West Virginia and being able
4 to narrow it down specifically to Cabell County.

5 **Q.** And did you also -- tasked to do research and offer
6 opinions on the trends, drug trends within --

7 **A.** To me, the trending were some of the most important
8 piece of this because, as an epidemiologist, I don't study
9 just the immediate problem, but we really are very
10 interested in the evolution of the problem and, as you'll
11 see, that was the part that I thought was some of the most
12 important stuff, is how the trends and how we basically
13 started off with an area that had very little drug problem
14 and now we have what we have.

15 **Q.** And we'll get to some specifics about that.

16 **A.** And get to some specifics --

17 **Q.** And what was your geographic --

18 COURT REPORTER: I'm sorry --

19 MS. KEARSE: I'm sorry.

20 COURT REPORTER: Can you start over with your
21 question? Thanks.

22 BY MS. KEARSE:

23 **Q.** Doctor, what was the geographic scope of your
24 assignment?

25 **A.** The geographic scope of my assignment was to look

1 specifically at Cabell County and sometimes data for Cabell
2 County was not available at that level because there were so
3 few opioid overdoses early on in the period that it was
4 essential to go back over time and, actually, for that, we
5 had to look at the whole state just to indicate what the
6 problem was.

7 **Q.** And did you issue a report of your research and
8 findings?

9 **A.** Yes, I did. It's contained in the report that I
10 delivered to you.

11 **Q.** Okay. And your report includes various graphs and
12 charts of your findings?

13 **A.** Yes, they do.

14 **Q.** And what I'll ask, I'm not going to hand you your
15 report right now so that we're not reading from it, but if
16 there's particular information or data that you think that
17 you need to refer to that, I would ask His Honor to allow me
18 to show that to you when we get to that point.

19 **A.** That would be important because, as an epidemiologist,
20 I want to make sure that I give you the exact number and
21 rather than a rounding number and sometimes I do need to
22 refer to my work.

23 **Q.** All right. Can you briefly -- let me ask you this.
24 What time period did you look at the data for this case?

25 **A.** After looking at this case, I wanted to go back as far

1 as I could in terms of understanding the development. So, I
2 went back to 1979 and then followed things forward from
3 there.

4 **Q.** And is it -- can you describe to the Court -- well, let
5 me ask you first. Did you look through basically two
6 different types of datasets?

7 **A.** Yes. The first thing is the -- the first one being
8 shown up on the slide, that was the most obvious source for
9 me to go to, was the fatal overdose data from Cabell County,
10 from the State Health Department of Vital Statistics. And
11 this was an effort at the very beginning. Once they started
12 noticing that there was an increase in drug -- and
13 particularly opioid-related deaths, they set up their own
14 data system because it took so long for them to get the data
15 back from the -- from the Vital Statistics Office, which is
16 all run centrally by the National Center for Health
17 Statistics.

18 **Q.** Okay. And we'll go into a lot more detail. I want to
19 talk about --

20 **A.** Yeah. And so, that's that detail. But, unfortunately,
21 that just started in 2001, but I wanted to go back further
22 than that to understand what was happening because we
23 already saw an increase there.

24 So, I looked at the period from 1979 to 2018 and there
25 we got -- looked for drug poisoning data from the Centers

1 for Disease Control for the State of West Virginia because
2 the main -- the main purveyor of all of the statistics is
3 the National Center for Health Statistics and they collect
4 it from the states.

5 And so, I was able to go back and get archaical
6 historical reports from there and able to reconstruct back
7 using the category of drug poisoning data. And maybe later
8 I can explain what the drug poisoning data is.

9 **Q.** We'll get to that.

10 **A.** Yes. But that's an important -- basically, opioid
11 overdoses are an important part of the drug poisoning data,
12 but there were so few opioid poisonings at that time that
13 the data we could only get was for this broad group that
14 included all drug poisonings because they suppressed the
15 numbers if it was less than five people.

16 **Q.** Okay. We'll get more specific about that. And,
17 generally speaking, did you focus on opioids or did you look
18 at all drug overdoses?

19 **A.** I looked at all drug overdoses but included opioid
20 because that was by far the largest number.

21 **Q.** Doctor, I'd like to talk about your methodology and
22 then we'll go into your opinions. And we'll probably get
23 through maybe the methodology now and then --

24 MS. KEARSE: Unless you want to break now.

25 THE COURT: This might be a good place.

1 MS. KEARSE: This is a short part, but it may --
2 yeah. It may go longer than five minutes.

3 THE COURT: Yes. Let's -- Dr. Smith, the wheels
4 of justice grind slowly in this court, so I'm going to ask
5 you to come back at 2:00.

6 THE WITNESS: Okay.

7 THE COURT: And I apologize for the two-hour
8 delay, but if you would come back at 2:00, we'll press on
9 with this and I look forward to hearing from you then.

10 We'll be in recess.

11 Mr. Farrell, do you have something?

12 MR. FARRELL: No. I'm just eager to stand in
13 recess.

14 THE COURT: All right. We'll come back at 2:00.

15 (Recess taken)

16 THE COURT: Dr. Smith, if you want to step back up
17 here, sir.

18 MS. KEARSE: Good afternoon, Your Honor.

19 BY MS. KEARSE:

20 Q. Dr. Smith, I want to talk a -- I have a couple of
21 questions just about some methodology. We'll move through
22 that.

23 Was your review of the state and national data
24 discussed earlier before we took the break part of your
25 methodology you used in carrying out your research in this

1 case?

2 **A.** Absolutely. Very standard methods.

3 **Q.** And now, if you'll talk a little bit more into the mic,
4 that would be great.

5 Are you familiar with the sources of the data that you
6 used in this case?

7 **A.** Yes, absolutely.

8 **Q.** And are you familiar with the methods in which the data
9 has been compiled that you reviewed?

10 **A.** Yes, I am.

11 **Q.** And are you familiar with some of the personnel who
12 have compiled the data?

13 **A.** Yes, I am.

14 **Q.** And, in your opinion, does the data provide a reliable
15 basis to determine the numbers of overdose deaths and drugs
16 identified in those cases?

17 **A.** Absolutely. Very standard methods.

18 **Q.** Doctor, did you use the same methods that you have
19 applied in your work in the field of epidemiology that you
20 did in this case?

21 **A.** Exactly the same.

22 **Q.** And are those methods generally accepted and reliable
23 in your field --

24 **A.** Very classic things.

25 COURT REPORTER: I'm sorry. What was that?

1 THE WITNESS: Very classic things.

2 BY MS. KEARSE:

3 Q. And I know it's going to be hard. I'll finish the
4 question and we'll try to get the court reporter not mad at
5 us by the end of the day or have a headache. No promises.

6 Have you used the same methods in your peer reviewed
7 articles that you have published about injury mortality
8 studies?

9 A. Yes, I have.

10 Q. And is this the same data and the same -- first of all,
11 I'll talk about the national data and the CDC data. Is the
12 CDC data the same type of data that you rely in your
13 research in academia?

14 A. Yes, it is.

15 Q. And the data that the research and epidemiologists such
16 as yourself, do you also rely on state data?

17 A. Exactly.

18 Q. I'd like to just talk a little bit about the state and
19 the national data. I want to first start with the state
20 data. Are you familiar with the state data in regards to
21 the methodology and collection that the Medical Examiner
22 provides regarding death certificates and death overdose
23 information?

24 A. Very familiar.

25 Q. And does the State of West Virginia have reliable

1 mortality data in regards to drug overdose fatalities?

2 **A.** We have very reliable and very sound statistics.

3 **Q.** I'd like to take a moment and explain to the Court a
4 typical overdose in regards to the information getting into
5 the data that we'll be looking at today.

6 MS. KEARSE: Gina, can you put up Exhibit -- Slide
7 number 3, please?

8 BY MS. KEARSE:

9 **Q.** Dr. Smith, does the State of West Virginia have a
10 statewide program for collecting overdose data?

11 **A.** Yes. It has one of the -- one of the few states with
12 such good reliable data.

13 **Q.** Okay. And can you go over for the Court -- and I'll
14 ask you to put the mic a little closer -- or pull the --
15 yeah. You could probably pull it there. Yeah. Thank you.

16 Can you explain to the Court how overdose fatality data
17 is collected and created in the State of West Virginia?

18 **A.** Right. Someone is found dead in an alley or in a house
19 and the EMT may be called. Then, if they feel the person is
20 very -- looks like they're actually deceased, they will
21 consult with a medical physician on call and between them
22 they will determine the person is dead.

23 Then a local Medical Examiner will be called and the
24 local county medical examiners, health professional people
25 with specialized training in decedent investigation, they

1 then collect scene information, take photographs, do very --
2 whatever is needed. And then they take blood samples.

3 And the body is sent to the OCME for autopsy and
4 toxicology. And in West Virginia they all go to the Central
5 Office here in Charleston. And then the detailed toxicology
6 is done. Medical Examiner records the causes of death on
7 the death certificate. And this is based on him looking at
8 all of the toxicology, all of the scene data, and in their
9 best professional opinion, they are a trained forensic
10 pathologist and they make this determination that this was a
11 drug overdose.

12 And then they write on the part of the death
13 certificate all of the drugs that they felt contributed to
14 the fatal overdose.

15 And then the data is sent -- the death certificate is
16 sent to the National -- the West Virginia Center for Health
17 Statistics, who then enter the data into the national
18 database and it's sent off to them for coding.

19 **Q.** And then the one part I did leave off of there after it
20 is coded and recorded in the State of West Virginia, is it
21 then sent to the CDC for -- to be placed in the national
22 database?

23 **A.** Sent off to the CDC for the national database and --
24 yes. And then there's a separate state database that's kept
25 internally.

1 **Q.** Okay. So, when we were talking about the state data
2 from 2001 to 2018, that would be this process?

3 **A.** Yes. Exactly the same process as is done there except
4 that, in West Virginia, they said, look, we're just
5 beginning to get an opioid epidemic out, getting a great
6 increase in cases. We need to understand this much more
7 rapidly.

8 So, as soon as they get the death certificate, they
9 enter it into the separate database that I use in my study
10 and so that they actually have the data to tabulate
11 themselves well before the official statistics get coded by
12 the National Center for Health Statistics.

13 **Q.** Thank you, Doctor. I want to talk specifically now the
14 overview of the data that you reviewed in this case and we
15 described earlier you looked at two datasets, one national?

16 **A.** Yes.

17 **Q.** All right. Can you tell the Court a little bit about
18 the -- I need to back this up -- the national data, the CDC
19 data, how is that compiled and what was your review of the
20 CDC data?

21 **A.** The CDC national data is compiled from the death
22 certificate data sent from all the states and, originally, I
23 understand they sent a hard copy certificate, but now they
24 send it to the CDC, it gets standard coding, and it's being
25 available as the main source of statistics and that's the

1 dataset that I was able to get data from 1979 to 2018.

2 These are the official statistics.

3 **Q.** And do the databases cover all types of overdose
4 fatalities?

5 **A.** Yes. They cover all fatalities from overdoses and all
6 drug poisoning data, as we technically call it.

7 **Q.** Now, Doctor, you don't personally review all the death
8 certificates yourself, do you?

9 **A.** No, I do not. There are very specialized people doing
10 this with a lot of training and they -- they do that.

11 **Q.** But the data allows you to review the historical deaths
12 and the drugs identified in the toxicology reports of those
13 deaths?

14 **A.** That's key. Exactly. I rely on people. I can't do
15 all the work myself and no one else does. We rely on the
16 official channel and the way the data is handled.

17 **Q.** And that's consistent with other epidemiologists who
18 would actually do this same type -- same type of research?

19 **A.** Yes, exactly. This is used by epidemiologists as part
20 of standard analyses for causes of death used all around the
21 world that same way.

22 **Q.** I'd like to first talk about the dataset that you
23 reviewed from 1979 to 2018 and that is this CDC data that
24 you described.

25 **A.** Well, the reason I went to that is that I felt it was

1 important to see what was going on just as the epidemic's
2 beginning. So, this data is vital statistics data.

3 And the interesting thing is when I went back to look
4 for it, there were so few overdose deaths from opioids that
5 I had to go to the next level of grouping that they do,
6 which was all accidental overdoses of which the drug
7 poisonings are part of. And that was essential for me to be
8 able to get a grouping so I could handle what -- so I could
9 look at what was going on in the early periods.

10 MS. KEARSE: Okay. Gina, if we could do Slide
11 number 5.

12 BY MS. KEARSE:

13 **Q.** I want to make sure the Court understands the
14 difference between the drug poisoning or drug poisoning data
15 versus having data of all the individual particular drugs
16 with that, too.

17 Doctor, I'm showing you a slide that's in your report.
18 Can you explain to the Court the poisoning data, how that is
19 applicable to the work that you've done in this case?

20 **A.** I felt this was absolutely key to understanding what
21 was going on earlier because I couldn't get -- there were so
22 few deaths that the CDC system wouldn't let me access
23 individual codes or individual like opioid poisonings
24 because there were so few, they grouped them.

25 This is for confidentiality reasons. If there are less

1 than five deaths in any category they won't release the
2 data.

3 And so, there's a grouping that we all use, which is
4 the category all drug poisonings, and this is one of my
5 former doctoral students who now is one of the senior people
6 in the Vital Statistics Office and she produces this in an
7 article which shows how the poisoning deaths are going up,
8 but when you look at it, the drug poisonings end up being
9 the major component of that.

10 So, that's why, when I was wanting to produce a
11 historical trend, I felt very confident that this was the
12 best way that we could really document in very firm numbers
13 what was going on in West Virginia.

14 **Q.** And so we're clear that the state data did not -- was
15 not collected until starting in 2001?

16 **A.** Yes.

17 **Q.** And so, this is really -- although we go up to 2018,
18 we're going to focus on the pre-2001 --

19 **A.** Exactly, because I think it was important for us to
20 understand was this a new problem we were seeing or had we
21 had it going on for years.

22 **Q.** And so, this is explaining that most accidental
23 poisoning deaths are drug poisoning deaths?

24 **A.** Exactly. The vast bulk of those are accidental
25 poisonings.

1 **Q.** And with your review of the CDC national data from 1979
2 to 2018, did you actually put a chart together of your
3 findings?

4 **A.** That was a key part of my report, yes.

5 **Q.** And I want to --

6 MS. KEARSE: Gina, if we can go to the next slide.

7 BY MS. KEARSE:

8 **Q.** Before talking specifically what this shows, I want to
9 make sure the Court understands what your process was in
10 your review and how you determined that this slide and graph
11 was applicable to overdose fatalities, drug overdose
12 fatalities.

13 **A.** When I've done this in other larger states, it was much
14 easier. You could go and extract the number and get it.
15 But the trouble is the number of deaths, because West
16 Virginia is a small state, was so small.

17 And as you can see there, I started off with 1979 data
18 and that up until 2000, you can see very clearly that the --
19 there were so few overdoses for the whole state that all it
20 could get was that broad category.

21 Of course, I tried to break it down to Cabell County
22 and there were just no deaths. They wouldn't give me the
23 data. So, I don't know what was going on.

24 But I do know that from 1979 to 199 -- to 2000, there
25 were less than 76 deaths a year for the whole state in this

1 drug poisoning category.

2 MS. KEARSE: Gina, can you go to Slide number 7?

3 And we may come back to this one.

4 BY MS. KEARSE:

5 **Q.** Doctor, Slide number 7 is an exhibit in your report and
6 it actually has some of the data in the left-hand side from
7 1979 to 2018 and this is age-adjusted rate data. Can you
8 explain to the Court what this slide shows?

9 **A.** Yeah. When I was going back over the historical data,
10 much of it was just actually an old pdf, copies they had of
11 old reports. So I had to actually go combing through and
12 find the page right off the bat that said West Virginia
13 data.

14 So, I copied that data down and they were much more
15 interested in the rates because they do comparisons with
16 other states. So, what you have here is the rate and the
17 age-adjusted rate is the standard practice that the CDC uses
18 to compare -- because they want to compare to some standard.

19 Because if you came from a state that was mostly old
20 people and you were looking at a disease that largely
21 affected young people, it would not be valid just to compare
22 the crude rate, the population, with another state.

23 So, they used the U. S. standard population to adjust
24 to what would have been the age-specific rates adjusted to
25 the U. S. standard population. It's a very standard

1 technique.

2 **Q.** And, Doctor, from your review of the CDC data and in
3 your graphs that you provided for the Court, what do you
4 conclude from the longer term data on the accidental drug
5 poisonings?

6 **A.** This broad category which I showed earlier includes the
7 drug poisoning and includes specifically opioid overdoses
8 was very relatively flat until 2000. And then, as you can
9 see here, the numbers just -- the rates increased very
10 dramatically.

11 **Q.** And so, the bottom part, just to be clear, up until
12 2000 you may not know particularly what drug this is but,
13 regardless it is very, very, very --

14 **A.** They're all in the same category, exactly, and that
15 category -- and you saw in the earlier slide the accidental
16 poisonings were driven by the drug poisonings. And we all
17 know clearly what's causing those increases here.

18 **Q.** And, specifically, this is a statewide review?

19 **A.** This part was a statewide review because I could never
20 get any -- as hard as I tried and I -- I combed through
21 state records. I combed everywhere trying to get some
22 specific data for Cabell County, but the numbers were just
23 so small I could never get hold of any data.

24 **Q.** I'd like to now talk about the national data. Is there
25 anything else you want to say about this particular data?

1 **A.** No, but I think I -- so, this is honing down on the
2 state and this is -- the most important piece of this is
3 this is using the same data collected over exactly the same
4 time periods so that you know exactly that everything is
5 constant and the rates are going up.

6 **Q.** And then, in the second database that we'll talk about,
7 it's going to be the state data, although the national data
8 still contains the information. And now, with the state
9 data starting in 2001, we'll talk about that.

10 **A.** Exactly.

11 MS. KEARSE: And, Gina, if we can go back to that
12 first slide or if we can put Slide number 8 on.

13 BY MS. KEARSE:

14 **Q.** I want to make sure -- I believe this was your
15 testimony. I want to make sure that we were clear on here
16 on the long-term trends and the overdose mortality. Is it
17 fair to say they show low and stable rates in West Virginia
18 from 1979 to 1999?

19 **A.** That's correct.

20 **Q.** And then followed by the increases that we saw as the
21 graph goes up?

22 **A.** Exactly. From 2020 [sic] on it started to -- from 2000
23 onwards it started to increase.

24 **Q.** Okay. And accidental poisoning deaths in West Virginia
25 were mostly due to drugs, had very low and stable rates.

1 Again, we just said that until 2001?

2 **A.** Exactly.

3 **Q.** All right. So, let's go to the state data. And the
4 state data is what we just went through the process of when
5 you told the Court about how that the data is collected and
6 then it's put into a database. Any drug that is on the
7 death certificate is then recorded; is that correct?

8 **A.** Yes. This is a very unique database that the state
9 created so that they would have their own timely data to be
10 able to see what was going on.

11 **Q.** And can you tell the Court what we're looking at on
12 Exhibit A? This is Exhibit A to your report, but is this --
13 first as to the time period, what is this time period?

14 **A.** This is the time period from 2001 until 2018 which, at
15 the time I prepared my report, was the most recent data
16 available.

17 **Q.** And so, 2001 to 2018, and then the next column says all
18 drug overdose deaths. Do you see that?

19 **A.** Yes.

20 **Q.** In the State of West Virginia from the data that you
21 reviewed, what was the number of total drug overdose deaths
22 from 2001 to 2018?

23 **A.** This is the data for Cabell County.

24 **Q.** Okay. And that's -- thank you, Doctor. So, that's --

25 **A.** This is in Cabell. So, as you can see, even in 2001,

1 when we had begun to get concerned about the drug overdose
2 problem, there were only 16 deaths in the whole county and
3 that's at the period when the curve is starting to go up in
4 my earlier graph. So, that -- that explains why I was
5 having so much trouble being able to get data for the
6 individual specific county because there were just so few
7 deaths.

8 **Q.** And thank you for -- this is specific to Cabell County
9 data?

10 **A.** This is very specific to Cabell County data and of
11 those 14 were -- the next column over is those that are
12 opioid-related.

13 **Q.** And can you briefly then just explain the chart as a
14 whole with that and then we'll go into the total
15 opioid-related. Are the following columns various
16 opioid-related drugs that were recorded on death
17 certificates?

18 **A.** Exactly. And -- and I really need to point out the
19 counts across further on, the individual drugs, most people
20 have multiple drugs. So, they wanted to know what drugs
21 were circulating, what drugs were causing it.

22 So, you might get two different opioids. You might get
23 five different opioids. It is just a matter of what was
24 recorded. But the actual number of people is only in the
25 first two columns.

1 **Q.** And for the opioid-related overdose deaths from 2001 to
2 2018, it looks like it's Column 3. Can you tell the Court,
3 what was the total number of overdose deaths in Cabell
4 County?

5 **A.** There were a total of 1,002 deaths from opioid-related
6 deaths.

7 **Q.** And do you know roughly what the percentage with that
8 would be, the 1,002 of the 1,151?

9 **A.** It's a large percentage. Just looking at it, it's
10 probably about 95 percent of the cases are opioid-related.
11 So, these are deaths where they have to have found at least
12 one drug that was an opioid and that, in the opinion of the
13 Medical Examiner, he felt that had a -- was significantly
14 contributing to the death.

15 **Q.** And so, this chart does not give us any information on
16 what was a valid prescription or diverted opioids, but this
17 is just looking at the toxicology reports and death
18 certificates?

19 **A.** We're looking at the actual drugs found, the actual
20 molecule found, and whether it was an illicit drug or not an
21 illicit drug. The same molecule will be there. When it's
22 ingested, the same molecule will be picked up in the
23 toxicology report.

24 **Q.** And to be -- we don't know the source of these things.
25 Again, this is your review of the toxicology?

1 **A.** It's impossible to tell the source from the toxicology
2 data.

3 **Q.** And did you also provide a chart and some graphics that
4 could show the Court what this data shows in regards to the
5 rise of opioids from 2001 and 2011?

6 **A.** Yes, I did.

7 MS. KEARSE: And, Gina, I'll go first to Slide 11.
8 This is more just for the record.

9 BY MS. KEARSE:

10 **Q.** I think, Dr. Smith, you mentioned you thought it was 95
11 percent. I think we calculated it -- or you had calculated
12 it at 87 percent?

13 **A.** Yes.

14 **Q.** Is that -- is that -- is 87 percent in your report?

15 **A.** Yes, that's correct.

16 **Q.** Okay. So, and just for the record for between 2001 and
17 2018, at least 1,151 people died of a drug overdose in
18 Cabell County?

19 **A.** I was reading from the -- I was reading from the opioid
20 -- from the wrong column. Yes, exactly. That's -- this is
21 the correct --

22 **Q.** All right.

23 MS. KEARSE: Gina, can you go to the next slide?

24 BY MS. KEARSE:

25 **Q.** And, Doctor, before we go into this -- well, let me ask

1 you this. Did heroin increase at some point in your review
2 of the data?

3 **A.** Yes. We really started to see the increase beginning
4 in 2011. And so, you can see the heroin is the blue line at
5 the bottom. That's heroin.

6 **Q.** So, for the data that the State of West Virginia has
7 and specific to Cabell County starting in 2001, can you
8 explain what the prescription opioid overdose deaths
9 compared to heroin and what this slide means for the Court?

10 **A.** To me, the most important thing on this slide is that
11 up until 2001, heroin was not much of a problem and, as you
12 could see, the red line is all of the prescription opioids.
13 And so, you'll see a very dramatic rise in prescription
14 opioids over the same period of time. And during this
15 period of time there was very little heroin certainly being
16 found in the people that had died.

17 MS. KEARSE: And, Gina, could we go to Exhibit A
18 again before that? I did want to explain one -- next before
19 that -- yea. And before that. Right.

20 BY MS. KEARSE:

21 **Q.** You've got on your slide a column for morphine and I
22 want to ask you that question because I do know we'll be
23 discussing it both from our perspective and questions by the
24 companies, as well, but is there any way to know whether or
25 not the morphine associated death was actually

1 heroin-related death or can you tell the Court a little bit
2 about what we may look at when we're looking at some of the
3 morphine?

4 **A.** You bring up a good point. What -- the concern is that
5 the heroin is then metabolized into morphine, but the
6 Medical Examiner goes to a lot of depth to determine as to
7 whether the drug overdose is due to morphine or heroin and
8 there are residues of heroin that they find in the drug and,
9 if that was found, then they would call that a morphine.
10 And if it was a -- yeah. Then they call that a heroin
11 death.

12 And so, there's a lot of evidence. There may be some
13 undercounting of the heroin deaths, but the number is
14 genuinely felt to be very small.

15 MS. KEARSE: Okay. Can we go back to Slide 12,
16 Gina?

17 BY MS. KEARSE:

18 **Q.** Okay. So, we've got -- was there anything else we
19 needed to talk about with this particular slide?

20 **A.** Yeah. No. So, to me, it obviously goes up and down
21 every year, but you can see there's clearly a very general
22 trend there of increasing involvement in this early period
23 of our epidemic that it was largely due to prescription
24 opioids.

25 MS. KEARSE: And can you go to the next slide,

1 Gina, please, number 13?

2 BY MS. KEARSE:

3 Q. Is this a summary of your 2001 and 2011 that we just
4 talked about?

5 A. Exactly, yeah.

6 Q. Okay. So, the reliable data shows that prescription
7 opioid deaths significantly exceeded illicit opiate deaths
8 in Cabell County during the years of 2001 to 2011; is that
9 your --

10 A. Absolutely.

11 Q. Can we go to the next slide and I want to go finish
12 from 2001 to 2018, your complete review. If you can explain
13 to the Court again what your findings are and what you did
14 to make this slide?

15 A. And what we do with it, so this is exactly the same
16 approach that we've now extended it out further and you can
17 see the earlier period that I described the rise of the
18 prescription opioids and then you can see it flattening out.

19 And the most important interesting thing to me, I was
20 surprised even when we looked at the data, that the
21 prescription opioids remained very flat. The number of
22 cases, deaths involving the prescription opioids.

23 And then along came heroin and you can see then you
24 start to see the deaths going up. And then, in 2013, along
25 came the clandestine overseas manufactured illicit fentanyl.

1 And there you saw the dramatic rise and -- in the fentanyl
2 and that was responsible for this large increase in the
3 overdose deaths.

4 **Q.** And, Doctor, do you have a rate of overdoses that has
5 changed over time between 2001 and 2018?

6 **A.** Yes, I have. It's actually in my report and I don't
7 remember that figure. As I mentioned earlier, I'm an
8 epidemiologist. I like to be true with my numbers and I
9 don't remember the exact figure, but it's a very dramatic
10 rise.

11 **Q.** For a specific number would it help to look at your
12 report?

13 **A.** It would be very helpful to look at my report.

14 MS. KEARSE: Your Honor, may I approach?

15 THE COURT: Yes.

16 BY MS. KEARSE:

17 **Q.** And this is just for -- on your report, did you
18 actually report on the overdoses that change over times in
19 regards to a percentage or number that you can provide for
20 the Court?

21 **A.** So, this is on Page 5 of my report. So, the rate of
22 fatal overdoses, this was for Cabell County, the previous
23 for Cabell County. The rate of fatal overdose increases
24 sharply over that time from roughly 16.6 per hundred
25 thousand in 2001 to a high of 2 --

1 THE COURT: Just a minute, Dr. Smith. Ms. Wu
2 wants to interject here.

3 MS. WU: Your Honor, we don't object to the
4 witness refreshing his recollection with his report, but we
5 do object to the witness reading his report into the record
6 as if it is evidence.

7 THE WITNESS: So, I -- I can --

8 THE COURT: Overruled. It's helpful to me for him
9 to explain what's in the report and if he needs to look at
10 it to do that, I don't have a problem with that. So, I will
11 overrule the objection.

12 MS. KEARSE: Thank you, Your Honor.

13 THE WITNESS: So, the rates increase from 16.6 to
14 213.9 per hundred thousand in 2017, which is a very large
15 increase. Almost 17 to almost 214.

16 MS. KEARSE: Gina, if we can go back to Exhibit A,
17 which is Page 9 of the chart, of the slide.

18 BY MS. KEARSE:

19 **Q.** On -- in this, Doctor, I want to ask you a question
20 about fentanyl and you have fentanyl starred there. Can you
21 tell the Court what -- what -- why does fentanyl have a star
22 there on -- on Page 9?

23 **A.** We definitely wanted to star fentanyl because fentanyl,
24 there is also a licit -- there is licit fentanyl from
25 patches from -- and that caused a few in the early periods

1 of that. But from 2013 onwards, the Centers for Disease
2 Control considers that was when the large influx of the
3 clandestine heroin being imported from overseas came in.

4 So, what we did is we considered any -- any of the
5 fentanyl prior to this 2013, when the big influx of imported
6 fentanyl, we considered that to be a prescription opioid.
7 And then, after that, we considered all of them to be a --
8 an illicit fentanyl.

9 **Q.** Doctor, in the work that you've done for this case,
10 have you formed an opinion as to whether or not there is an
11 ongoing role of prescription opioids as a cause of drug
12 overdose mortality in the Cabell-Huntington community?

13 **A.** Yes. The most important -- if you look at the graph,
14 there is an increase and there is a very continued presence
15 of illicit -- of both -- of opioids and prescription opioids
16 over this period of time.

17 MS. KEARSE: And if we can go back to Figure 2,
18 Gina, on Slide 12 and Slide 14.

19 BY MS. KEARSE:

20 **Q.** And does this also show -- the prescription opioids,
21 it's going down at some point in 2018?

22 **A.** Yes.

23 **Q.** I want to talk to you about the role, though, that you
24 -- on prescription opioids still playing a part in overdose
25 deaths. Have you researched literature or familiar with

1 some of the literature that looks into West Virginia data in
2 regards to examining overdose fatalities and records similar
3 to your review?

4 **A.** Yes, we have.

5 **Q.** Okay. Could you tell the Court a little bit about
6 that? And we'll show a couple documents.

7 **A.** Yeah. So, the most important thing is that there's
8 well-documented studies that have been done. The clear
9 presence, continued presence of prescription opioids being
10 included in the mortality deaths that occur in the state,
11 and they still very much still occur even in the most recent
12 data.

13 **Q.** And in your report you talk about a study in 2008 that
14 was published in JAMA. I would like to show that to you and
15 have you talk to the Court about that.

16 **A.** Exactly, yes.

17 **Q.** Why don't you explain to the Court what -- what's the
18 study that you relied on in offering your opinions about the
19 use of prescription drugs within the overdoses?

20 **A.** The most important part about this study, and it was
21 really a landmark study where they took a look at -- they
22 took the 2016 -- all the deaths that occurred in the state
23 from drug overdoses.

24 **Q.** And so -- I'm sorry. That may be confusing. 2008?

25 **A.** That was 20 -- the article was published in 2008, but

1 they took 2006 deaths.

2 **Q.** Right. Okay. Let me do this.

3 MS. KEARSE: Your Honor, may I approach?

4 THE COURT: Yes.

5 BY MS. KEARSE:

6 **Q.** This won't go into evidence as an article. I would
7 like to show P-43566. Can you let the Court know what this
8 article is and what it is intended to study?

9 **A.** So, this is an article that was published in JAMA and
10 it was an article published by a crew from the Centers for
11 Disease Control who came out to assist the State in
12 determining and understanding the drug problem in the state.

13 **Q.** P-43566.

14 **A.** And so, what they did is they took a -- all of the
15 death certificates that occurred in 2006 from the -- from
16 the Vital Statistics Office and then tracked back to the
17 Medical Examiner's Office to get the detailed toxicology on
18 these.

19 And then the other very important piece was that they
20 determined whether the person who died had a -- any record
21 in the Prescription Drug Monitoring Program in the state.
22 And this was set up in 2003 and they went -- and so, over --
23 whether there was any prescription in the chart and then
24 they also looked at whether there was a current prescription
25 which was within -- the standard is within the past 30 days.

1 Q. And I want to make sure the record is clear. This is
2 an article entitled *Patterns of Abuse Among Unintentional*
3 *Pharmaceutical Overdose Fatalities* published in the American
4 Medical Association Journal of 2008?

5 A. That's correct.

6 MS. KEARSE: And I want to go just really -- just
7 in the box there, Gina, if we move to the top.

8 BY MS. KEARSE:

9 Q. The context, I think you just talked about. This is --
10 well, if you can tell the Court about the context.

11 A. So, the context was that the rural states like West
12 Virginia had experienced the largest increase in the drug
13 overdose mortality during this period of time. And you'll
14 see this is early in the outbreak that they were concerned
15 about what was going on and happening.

16 And so, it's basically to evaluate the risk
17 characteristics of people dying from unintentional
18 pharmaceutical overdose, the types of drugs, and the role of
19 drug abuse and the deaths. And the key thing was that they
20 were looking at prescription drugs and whether the people
21 had a prescription for that drug.

22 MS. KEARSE: And can we go to the results, Gina?
23 I'm sorry. Still on Page one. In the box. Yes.

24 BY MS. KEARSE:

25 Q. And you mentioned there was a review of -- was it 295

1 death certificates within the State of West Virginia?

2 **A.** Yes.

3 **Q.** And although this is state data, would this encompass
4 Cabell County?

5 **A.** Yes. Exactly. The county is not specifically
6 identified with the entire state.

7 **Q.** And this is a study that you've been familiar with in
8 your work and role as an epidemiologist in the State of West
9 Virginia?

10 **A.** I was very familiar. In fact, I've actually been in
11 contact with the author because I was keen to try and get
12 some more understanding of how it came about and the origin
13 of all of that.

14 **Q.** And what's different from this review, I want to make
15 sure I understand it, in your review from the 2001 all the
16 way to 2018 with the state data, we were looking at death
17 certificates only; is that correct?

18 **A.** Yes. We were relying just on what's in the death
19 certificate.

20 **Q.** And this study went a step further and actually matched
21 it up to other pharmaceutical reporting through the
22 monitoring system; is that correct?

23 **A.** Exactly. And the other piece of it that's really
24 significant is that this validated this whole process and
25 showed how reliable the data was that actually makes it onto

1 the death certificate. But we went back and checked
2 everything and it's very reliable.

3 **Q.** And can you read the results for the Court and for the
4 record on the finding from this review and research done in
5 2008, published in 2008, regarding 2006 death certificates
6 in the State of West Virginia?

7 **A.** So, of the 295 decedents, 198, 67.1 percent were men
8 and 271 or 91.9 percent were aged 18 to 54 years.

9 Pharmaceutical diversion was associated with 186 or
10 63 percent of deaths, while 63 or 21.4 percent were
11 accompanied by evidence of doctor shopping. And doctor
12 shopping, I'll just clarify, doctor shopping is where they
13 were going around to multiple doctors for the same
14 prescription in the same period of time.

15 Prevalence of diversion was greatest amongst those 18
16 to 24 years and decreased across each successive age group.

17 Having prescriptions for a controlled substance from
18 five or more clinicians in the year prior to death, which is
19 what they were calling doctor shopping, was more common
20 amongst women and amongst decedents aged 35 to 44 years
21 compared with men. There was 33 or 16.7 percent in other
22 age groups.

23 Substance abuse indicators were identified in 279
24 decedents, with -- which was 94.6 percent with non-medical
25 routes of exposure and illicit contributory drugs

1 particularly prevalent among drug diverters.

2 Multiple contributory substances were implicated in 234
3 or 79.3 percent. And I think that's a very important part.

4 And opioid analgesics were taken by 275 percent,
5 93.2 percent of whom only 122, which was 44.4, had ever been
6 prescribed these drugs.

7 MS. KEARSE: Gina, if you can go to Page 2 and
8 just that upper part during -- yes.

9 BY MS. KEARSE:

10 **Q.** I just want to make sure that we're clear on the
11 purpose for the study there and just to the -- the first two
12 sentences of this.

13 **A.** During 1999 to 2004 West Virginia experienced the
14 nation's most substantial increase, a 550% increase, in
15 unintentional poisoning mortality. So, you see, they're
16 talking of this group of unintentional poisoning mortality
17 and then when they broke it down, the vast bulk of those are
18 opioids.

19 **Q.** Were they referring to the CDC data in that statement?

20 **A.** Yes, exactly.

21 **Q.** And the state vital records?

22 **A.** Yes. The state vital records indicate that the
23 increase in drug overdose mortality rates continued after
24 2004. Therefore, they -- that's what's the whole object of
25 this study.

1 **Q.** So, therefore, we conducted a study to better
2 understand these unintentional drug poisoning deaths and
3 that's what this paper is about?

4 **A.** Exactly.

5 **Q.** Okay. And this paper was part of your research into
6 your opinions in this case?

7 **A.** Yes, it was, because it illustrated very well the
8 methodology that I used in my study.

9 **Q.** And so we're clear, what does this research and the
10 other research that you've done mean to you in regards to
11 prescription opioids?

12 **A.** This was really the first good study that documented
13 the role of prescription opioids and the drug overdoses in
14 West Virginia. The other significant feature was published
15 in JAMA, which is one of the leading medical journals in the
16 world, and it was done by a very skilled group of
17 epidemiologists for the Centers for Disease Control.

18 **Q.** Doctor, I would like to turn to one other study that
19 you reference in your report and that the Court has heard a
20 little bit about that, but are you familiar with a 2016
21 study by the West Virginia Department of Health and Human
22 Resources --

23 **A.** Yes, I --

24 **Q.** -- regarding overdose fatalities?

25 **A.** Very familiar.

1 MS. KEARSE: Gina, if you could put on the slide
2 44211.

3 May I approach, Your Honor? It's already been entered
4 in as an exhibit, Your Honor.

5 BY MS. KEARSE:

6 **Q.** Doctor, I would like for you to tell the Court how are
7 you familiar with this study in your position in
8 epidemiology?

9 **A.** It was one of the -- I actually know the people
10 personally that conducted the study and I was part of a
11 group just as I came to the state when they actually
12 released the results of this and it was exactly the kind of
13 study that I felt the State needed to be done. And so, that
14 was why.

15 And it follows up very well. I call this the link
16 study because it linked together the data that was available
17 in different sources.

18 **Q.** And is it similar to the 2008 publication into what
19 they were looking into or linking or is there additional
20 information?

21 **A.** It used the exact same methods as the 2008 study.

22 **Q.** And then similar, they did a detailed analysis of the
23 drugs that were found in death certificates for 2016?

24 **A.** Exactly. They took all the death certificates
25 identified from the Vital Statistics Office and tracked back

1 to the Medical Examiner's Office and then tracked back that
2 person's prescription record in the Prescription Drug
3 Monitoring Program.

4 **Q.** And this document, the 2016 West Virginia Overdose
5 Fatality Analysis, is this an official government document
6 by the State of West Virginia?

7 **A.** This is an official document available on the website
8 from the -- from the --

9 **Q.** I would like to draw your attention just to one part of
10 the publication on the Executive Summary. If we can go to
11 Line 2 to the purpose of the report. Does this comport to
12 your understanding of the report? The purpose of this
13 report is to study West Virginia overdose deaths to identify
14 opportunities for intervention?

15 **A.** Absolutely. That was the whole point of doing this, as
16 I -- is that the State is saying how can we use this to our
17 planning to understand what's going on.

18 **Q.** And were there key findings of this report that you
19 included in your reporting in your opinions in this case?

20 **A.** Yes, I did because I felt it was very important to show
21 how the Medical Examiner data was used and they were able,
22 because it was a much more in-depth study, to take the vital
23 statistics data and give it some life and meaning and seeing
24 what was going on.

25 **Q.** So, both --

1 MS. KEARSE: And, Gina, I will go down to the last
2 paragraph.

3 BY MS. KEARSE:

4 Q. But before that, so the Court understands, though,
5 we've looked at overall data and then there's two sets of
6 data that did much more in-depth with the Medical Examiner
7 data plus; is that correct?

8 A. Yes.

9 Q. And were there key findings in this study that you've
10 relied on in your opinions?

11 A. Yes. This to me was absolutely -- and I would just
12 point out for the clarity of the Court that as a generic
13 thing we call them Prescription Drug Monitoring Programs,
14 but the name of the West Virginia one is called the
15 Controlled Substances Monitoring Program. It is exactly the
16 same as if I called the PDMP.

17 And so, when they went back to look for the dispensing
18 of Schedule II to IV controlled substances, 93 percent of
19 decedents had a documented history of a prescription in the
20 -- in the CSMP and, to me, that was very significant, that
21 these people clearly were being prescribed opioids.

22 And in the 30 days prior to death, nearly half of the
23 females and 36% of the males actually had a current
24 prescription within the 30 days, which is considered
25 current. If they filled a prescription, you can only get a

1 30-day prescription at a time.

2 **Q.** Thank you. Now, with this report --

3 MS. KEARSE: You can go to the next slide, Gina.

4 Slide number 18.

5 BY MS. KEARSE:

6 **Q.** I believe this is the data you just read. I just want
7 to make sure we're on -- what you reported in your report,
8 is this some of the data that we just read into the record?

9 **A.** This is exactly the summary from my report where of the
10 830 overdoses, 91 percent had a prescription record, and the
11 key thing is also this current prescription that -- here and
12 49 percent of females and 36 percent of males.

13 **Q.** And so what did -- Doctor, what did you conclude from
14 this study?

15 **A.** What I concluded is that prescription drug overdoses --
16 that the overdose problem in West Virginia was -- had a very
17 important component of it due to prescription drugs, very
18 commonly found prescription drugs, and that many of these
19 people actually had a history. 91 percent of these people
20 had a history of actually being prescribed drugs involved in
21 overdoses.

22 **Q.** And so, the ten years earlier was a CDC study; is that
23 correct?

24 **A.** Yes.

25 **Q.** And then ten years later was a State of West Virginia

1 study?

2 **A.** Finding exactly very similar kinds of findings.

3 **Q.** And are these two studies amongst your other research
4 the basis of your opinions that prescription opioids
5 continue to play a major role in overdose fatalities even
6 after increase of fentanyl and heroin were tallying?

7 **A.** Absolutely. And we find even --

8 MS. WU: Your Honor --

9 THE COURT: Ms. Wu?

10 MS. WU: We object to the leading question.

11 THE COURT: Well, try not to lead him, Ms. Kearse.

12 MS. KEARSE: I'm trying to wrap it up. Right.

13 BY MS. KEARSE:

14 **Q.** Dr. Smith, what is your opinion regarding the ongoing
15 role of prescription opioids in regards to overdose
16 fatalities?

17 **A.** My conclusion from reading the literature, looking at
18 my own reports and what I found, was that there was a very,
19 very conclusive evidence that prescription drug --
20 prescription drugs and prescription opioids in particular
21 play -- continue to play a very important role in the drug
22 overdose deaths in West Virginia.

23 THE COURT: Even with the increase of heroin
24 deaths?

25 THE WITNESS: Even when you look at the increase

1 in heroin. Most of these deaths they find multiple drugs,
2 including prescription drugs, classic prescription drugs,
3 and that was a surprising thing to me, is that I -- and in a
4 way it's no surprise because if you look at even some of the
5 famous sort of pop stars and things, many of them are buying
6 pills that they look like prescription drug pills, but they
7 contain fentanyl in them. And so, the drugs are being mixed
8 together.

9 MS. KEARSE: Excuse me, Your Honor.

10 (Pause)

11 BY MS. KEARSE:

12 Q. Doctor, have all your opinions today been given to a
13 reasonable degree of professional certainty?

14 A. Yes, they have.

15 Q. And with your continued work in West Virginia, are you
16 still very much involved in researching the opioid epidemic?

17 A. Very much so. It's very much current and ongoing.

18 Q. And does that research still involve the involvement of
19 prescription opioids?

20 A. Absolutely.

21 MS. KEARSE: Thank you, Your Honor. I have no
22 further questions.

23 THE COURT: All right. Ms. Wu?

24 MS. WU: Yes.

25 THE COURT: Are you next?

1 MS. WU: I am up.

2 THE COURT: We have to give the defendants a crack
3 here, Dr. Smith.

4 MS. WU: Judge, may I proceed?

5 THE COURT: Yes.

6 **CROSS EXAMINATION**

7 **BY MS. WU:**

8 **Q.** Dr. Smith, I'm Laura Wu, counsel for McKesson in this
9 case. We actually met by Zoom back in September at your
10 deposition. It's nice to see you in person.

11 **A.** Nice to see you again.

12 **Q.** So, I'm going to pick up on a few of the matters that
13 you discussed with Ms. Kearse and I promise this will be
14 relatively brief.

15 So, you just told counsel for the plaintiffs that you
16 did not study the source of any of the opioids involved in
17 the overdoses that found -- that form the matter of your
18 testimony in this case, correct?

19 **A.** By the source, do you mean whether they came directly
20 from a prescription or whether they came from a -- from an
21 illicit source?

22 **Q.** The origin, whether it be a drug trafficking
23 organization or a pharmacy, that is?

24 **A.** No. As I say, we are just looking at the molecules
25 that the toxicologists find in the body and we have no idea

1 where those molecules came from.

2 **Q.** And so, it follows that you don't offer any opinion as
3 to the relationship between the defendants in this case and
4 any of the overdoses referenced in your opinions in this
5 case, correct?

6 **A.** I'm just describing the drugs that are involved in the
7 death. That's all I can say.

8 **Q.** So, Doctor, I'd like to start by asking you some
9 questions about the early period in your opinions, the
10 period 1979 to 2001, and you've offered opinions about the
11 accidental poisoning rate in the State of West Virginia as a
12 whole, correct, Doctor?

13 **A.** That's correct.

14 **Q.** And you haven't offered any opinions that are specific
15 to Cabell County for that period?

16 **A.** We -- the deaths were so low we were not able to get
17 any data from there.

18 **Q.** And as you've described in your testimony with
19 plaintiffs' counsel, drug-related -- drug-related poisonings
20 are a subset of the accidental poisoning data that you
21 showed the Court a short while ago?

22 **A.** Yes.

23 **Q.** And opioid-related poisonings are a subset of those
24 drug-related poisonings, correct?

25 **A.** That's correct.

1 **Q.** And you are offering no opinion in this case on the
2 number of opioid-related poisonings in the State of West
3 Virginia for the period through 2001, correct?

4 **A.** The only opinion I am offering is that the
5 opioid-related poisonings are contained within that group.
6 And so, the opioid poisonings would be lower than that group
7 but they would be contained in that group.

8 **Q.** Okay.

9 **A.** So, there's still evidence that they couldn't be hidden
10 anywhere else in any coding system. So, they're definitely
11 within that group.

12 **Q.** And no opinion you offer is specific to that group of
13 overdoses, correct?

14 **A.** That was not possible.

15 **Q.** And you're offering no opinion as to the number of
16 prescription opioid overdoses for the period prior to 2001,
17 correct?

18 **A.** That is correct.

19 **Q.** Okay.

20 **A.** Just the -- just the -- they would have been in there
21 somewhere.

22 **Q.** Okay. And you just don't know how many based on the
23 data you've reviewed for this case, correct?

24 **A.** No. The only thing I do know is that for the whole
25 state there are less than 75.

1 **Q.** So, prior to 2001, there were fewer than 75
2 prescription opioid overdoses prior to 2001; is that
3 correct?

4 **A.** That would be -- that would have to be somewhere in
5 that group, yes. There could never be more than that.

6 **Q.** So, now I'd would like to move forward in time and talk
7 a little bit more about your opinions which picked up in
8 2001 through 2018. And that's the period that is shown in
9 -- I think it was Figure 2 which you looked at with Ms.
10 Kearse and I think maybe it would be easiest if we use the
11 -- here we go. There it is. I'm going to borrow counsel's
12 demonstrative to look at it.

13 Doctor, it's your opinion that after 2011, you observed
14 a new trend, which was that heroin and illicit fentanyl
15 drove the overdoses in Cabell County, correct?

16 **A.** That's correct.

17 **Q.** Okay. So, now I would like to talk more about the way
18 that you identified the drugs involved in the overdoses
19 shown in Figure 2 to your report which you've testified
20 about today.

21 Doctor, for each of the overdose deaths the data that
22 you relied on which you just discussed with Ms. Kearse
23 identifies the immediate cause of death derived from the
24 underlying death certificates, correct?

25 **A.** Yes.

1 **Q.** And the data you rely on, as you described, may also
2 rely on other factors which contributed to the death,
3 correct?

4 **A.** There were two parts to the death certificate. There's
5 one -- those that were immediately -- caused the death, and
6 that's the drugs that are being reported that we're talking
7 about. And then, there is another section of the death
8 certificate that are factors that could be related.

9 **Q.** And so, the overdoses which are charted in your Figure
10 2 as shown to the Court, those are the overdoses which track
11 to the information that the Medical Examiner provided for
12 the cause of death, correct?

13 **A.** Correct.

14 **Q.** In the case of drug overdoses, the Medical Examiner --
15 Examiner may count up a number of contributing factors for a
16 death, correct?

17 **A.** There are some -- yeah. There are sometimes some
18 contributing factors.

19 **Q.** And those are not charted in your Figure 2, correct?

20 **A.** No, they're not.

21 **Q.** Doctor, a toxicology screen on its own can't determine
22 the cause of death, correct?

23 **A.** That's correct.

24 **Q.** More information than just a tox screen is required in
25 order for the Medical Examiner to make a reliable

1 determination, correct?

2 **A.** Correct.

3 **Q.** And, in fact, it's the practice of the West Virginia
4 Office of the Chief Medical Examiner to identify all drugs
5 thought to have contributed to a death on the death
6 certificate, correct?

7 **A.** They list all drugs -- if you read that section of the
8 death certificate, it says the disease or injury that caused
9 the death. That is actually the -- I might have missed out
10 a word, but that's almost the exact wording of it. It's the
11 injury -- it's the condition, disease or injury, and
12 poisoning is part of injuries, that caused the death.

13 So, these are the drugs that in the opinion of the
14 Medical Examiner all of the drugs were involved in causing
15 the death rather than just a contributing factor.

16 **Q.** In cases in which multiple drugs are involved in an
17 overdose, Doctor, it can be difficult for the Medical
18 Examiner to determine the drugs which caused the death,
19 correct?

20 **A.** Yes.

21 **Q.** In fact, I believe you previously told me that it's
22 almost impossible to determine the cause of death in an
23 overdose situation, which is -- involves polypharmacy or
24 multiple drugs, correct?

25 **A.** I think if I remember correctly from what I said is --

1 and certainly what I would say now is that it's in their
2 opinion all of these drugs significant -- contributed to the
3 death and that it is not -- it is not -- you cannot select
4 which one, or any one didn't, but he also believes that each
5 of them made a significant contribution. Otherwise, they
6 would not have been listed in that. And that's after expert
7 opinion.

8 **Q.** And, Doctor, just for clarity, the "he" that you are
9 referencing in your answer would be the Medical Examiner,
10 correct?

11 **A.** Yes, correct. It would all be males since -- since the
12 history of West Virginia.

13 **Q.** I didn't know that, but I just wanted the record to be
14 clear.

15 **A.** But there are women Medical Examiners and you've
16 probably seen them on TV.

17 **Q.** Thank you, Doctor.

18 THE COURT: I'm sure that will change over time.

19 BY MS. WU:

20 **Q.** Doctor, polypharmacy overdoses are quite common in West
21 Virginia, correct?

22 **A.** Correct.

23 **Q.** In fact, three quarters of fatal overdoses that
24 occurred just in the period 2005 through 2017 involved
25 multiple drugs, correct?

1 **A.** Correct.

2 **Q.** So, Doctor, you've offered opinions about overdoses
3 including -- with a contributing cause of prescription
4 opioids and I'd like to talk a little bit more about those
5 prescription drugs.

6 Doctor, you're a practicing physician, correct?

7 **A.** I'm not a practicing physician. I'm a physician
8 epidemiologist and I -- I don't prescribe now. I used to in
9 my former life, but --

10 **Q.** You were a trained physician, I'll say.

11 **A.** Yes, I am a trained physician. Thank you.

12 **Q.** Thank you, Doctor, for that correction.

13 Doctor, a prescribing physician is in the best position
14 to evaluate the risks and benefits of prescribing any
15 specific drug to a patient, correct?

16 **A.** If they have access and knowledge of the best practices
17 and the risks involved.

18 **Q.** And one of the risks that a physician may consider is
19 the risk of addiction, correct?

20 **A.** Correct.

21 **Q.** Unlike doctors, wholesale distributors, McKesson, ABDC,
22 Cardinal, and others, are not in a position to evaluate the
23 risk of addiction for any individual patient, correct?

24 **A.** They don't get involved. They're like epidemiologists.
25 They do not get involved in individual patient decisions.

1 Q. They don't have access to individual patients, correct?

2 A. Unless they're using a database to look at things, no.

3 Q. And your report, which you discussed earlier,
4 identified the number of fatal overdoses in Cabell County
5 that you attribute to prescription opioids, correct?

6 A. Yes.

7 Q. In reviewing the overdose deaths for Cabell County that
8 you attribute to prescription opioids, you did not consider
9 whether the individual used prescription opioids as
10 prescribed by a physician or other prescriber, correct?

11 A. We didn't have access to that data.

12 Q. And conversely you didn't consider whether the
13 individual who used the drug involved, that prescription,
14 used the drug in a non-prescribed manner, correct?

15 A. We don't have that information.

16 Q. In reaching your conclusions about overdoses in Cabell
17 County, you didn't attempt to determine how many, if any of
18 the overdose deaths that form your opinions, were associated
19 with prescription opioids that had been prescribed
20 legitimately?

21 A. We did not do that. I thought it was adequately
22 covered by the two earlier studies and that's why I
23 introduced that.

24 Q. That's not work that you've done in this case to offer
25 opinions specific to Cabell County, correct?

1 **A.** Not specific for that county.

2 **Q.** And, likewise, in reaching your conclusions about
3 overdoses in Cabell County, you didn't determine how many of
4 the overdoses you observed were associated with prescription
5 opioids that had been accessed through illegal means,
6 correct?

7 **A.** I did not have any knowledge of the origin of the
8 molecules involved in the causing of death.

9 **Q.** So, Doctor, I'd like to talk a little bit more about
10 the way that you identified illicit narcotic overdoses to
11 form your opinions in this case.

12 So, Doctor, you offered the opinion that there were
13 relatively few overdoses caused by illicit opioids like
14 heroin and fentanyl up through the period 2011, correct?

15 **A.** That's correct.

16 **Q.** In forming your opinions you relied on data which
17 summarized information from death certificates, correct?

18 **A.** I relied on the data, the drugs listed in the death
19 certificates.

20 **Q.** And you, yourself, relied on datasets rather than
21 reviewing the underlying death certificates, correct?

22 **A.** I -- I am an epidemiologist. I rely on experts all the
23 way along the way that I work with. You don't rely on
24 checking the farm or every piece of food you eat. So, we
25 rely on experts to do their job and I know that the people

1 are experts and so I didn't, no.

2 **Q.** So, you personally didn't review any of the death
3 certificates that formed the basis of the data for your
4 opinions in this case, correct?

5 **A.** No, I did not.

6 **Q.** Doctor, are you aware that Cabell County produced death
7 certificates for overdoses for the period 2006 to 2020?

8 **A.** I'm aware that the County has death certificates, gets
9 a copy of the raw death certificates, but they're not
10 involved in the data analysis, coding and compiling of it
11 like that, but there are physical death certificates filed
12 there, yes.

13 **Q.** And you didn't review those death certificates in
14 connection with your work in this case?

15 **A.** I did not see any need because experts had already
16 extracted the data for me.

17 **Q.** Doctor, you just described in your testimony with
18 plaintiffs' counsel heroin can be difficult to detect in
19 fatal overdoses, correct?

20 **A.** Yes.

21 **Q.** That's because heroin metabolizes into morphine and
22 another chemical, 6-Monoacetylmorphine, correct?

23 **A.** Correct.

24 **Q.** And for ease, can we agree to call that 6-MAM?

25 **A.** Yep.

1 Q. Okay. So, the chemical 6-MAM is difficult to detect in
2 very small quantities, correct?

3 A. I'm not an expert toxicologist, but I do understand
4 there are some difficulties.

5 Q. And you're aware of those difficulties because they're
6 commonly discussed in the academic literature, correct?

7 A. Correct.

8 Q. And because the fact that 6-MAM is difficult to detect
9 in small quantities, it can be difficult to determine when
10 an individual ingested morphine, a prescription drug, as
11 compared to heroin, which has been metabolized in the body,
12 correct?

13 A. That's correct.

14 Q. As a result, you're aware that heroin deaths may be
15 undercounted, correct?

16 A. Yes.

17 Q. Doctor, in connection with your analysis of overdoses
18 in Cabell County, you counted morphine-related overdoses as
19 prescription opioid-related deaths, correct?

20 A. Yes.

21 Q. Doctor, you don't know how many fatal overdoses caused
22 by heroin were incorrectly reported as caused by morphine,
23 correct?

24 A. The exact number, I do not know, but I do know that a
25 lot of effort is spent at the Medical Examiner's Office

1 trying to determine that. They also rely very much on the
2 scene information. So, it's not just entirely a
3 toxicological decision.

4 **Q.** You just don't know as you sit here today how many
5 heroin deaths may have been miscounted as a prescription
6 opioid or morphine-related death, correct?

7 **A.** No. I don't know the exact number.

8 **Q.** Okay.

9 MS. WU: Could we look at DEF-WV-00131? And I'm
10 just going to hand it out in paper.

11 Your Honor, may I approach?

12 THE COURT: Yes.

13 BY MS. WU:

14 **Q.** Doctor, do you have in front of you DEF-WV-00131?

15 **A.** Yes.

16 **Q.** Okay, thank you.

17 Doctor, this is a death certificate issued by the West
18 Virginia Medical Examiner, correct?

19 **A.** Yes.

20 **Q.** This is the type of individual death certificate that
21 records the information that, once summarized, makes up the
22 data that you reviewed in this case, correct?

23 **A.** That's correct.

24 MS. WU: Your Honor, I would move to admit
25 DEF-WV-00131 into the record.

1 THE COURT: Is there any objection?

2 MS. KEARSE: I'm looking at the document. I
3 wanted to make sure there's no sensitive information on
4 there.

5 MS. WU: So I -- to address that point, counsel
6 and Judge Faber, I do have a version of this document which
7 redacts the individual information for the decedent and I
8 would, with the Court's permission, ask that I provide a
9 redacted version to counsel and the Court for purposes of
10 the record given the sensitive nature of the document.

11 THE COURT: You're just offering this as an
12 example of what a death certificate is?

13 MS. WU: Yes, Your Honor. I will be discussing
14 some aspects of it, but nothing which would identify the
15 individual, and I will be very careful about that.

16 MS. KEARSE: And that was my thing about that,
17 Your Honor. I don't know if this just is an exemplar with
18 an empty one or if there's specific information within the
19 death certificate and so, it's hard to note my objection,
20 but I also note there's sensitive information in there, as
21 well.

22 MS. WU: Your Honor, with the Court's permission
23 with counsel, I can submit a redacted version which would --

24 THE COURT: Do you have any problem with that, Ms.
25 Kearse?

1 MS. KEARSE: Yeah. I just don't know the purpose
2 for what it's being offered, Your Honor. If it's exemplar
3 of what a death certificate looks like, that's fine. If
4 there's specific information on there, I have not heard that
5 information.

6 MS. WU: Is there an objection to the document?
7 I'm happy to clear it up.

8 MS. KEARSE: If it's a blank death certificate to
9 show what a death certificate looks like, I'm fine with
10 that.

11 MS. WU: We will be discussing certain aspects of
12 it. I am happy to go through it and move it in. It is a
13 public record of a vital statistic and, for that reason, is
14 admissible.

15 Might I approach, Your Honor?

16 THE COURT: Well, if you're just offering it as an
17 example of a death certificate and questioning him about it,
18 why do you need it actually admitted into evidence?

19 MS. WU: Your Honor, I will be questioning about
20 some of the substantive information provided by the Medical
21 Examiner in this document. I won't be tying it to the
22 decedent's name.

23 THE COURT: Mr. Farrell?

24 MR. FARRELL: Yeah. So, I believe this is a
25 public record. And so, without knowing more, I think

1 somebody from the general public could probably go and see
2 that this 27-year-old from West Virginia, from Huntington,
3 West Virginia, died from a morphine intoxication.

4 I believe counsel is trying to elicit the point that
5 there are certain classifications in these reports that are
6 omnibus and are not necessarily able to relate to heroin
7 versus prescription opioids.

8 That being said, we've been prohibited from telling
9 stories of this 27-year-old who died from an opioid overdose
10 and she wants to introduce his death certificate.

11 MS. WU: Your Honor --

12 MR. FARRELL: So, I believe she can make her point
13 without introducing as evidence in this case the death of
14 this 27-year-old.

15 THE COURT: Well, that was the point I was trying
16 to make, Ms. Wu. Why do you need it in if you -- this is
17 just an example?

18 MS. WU: Your Honor -- Your Honor, this is -- I
19 will not be discussing the individual decedent here.
20 However, the information provided by the Medical Examiner in
21 terms of the categorization of the death which feeds
22 directly to the datasets which this witness has used are
23 relevant to testing the reliability of his opinions in this
24 case.

25 THE COURT: Okay. I'm going to admit it. The

1 objection is overruled. It's admitted.

2 MS. WU: Thank you, Your Honor. May I approach
3 with a redacted version for the record?

4 THE COURT: Yes.

5 MS. WU: Thank you.

6 THE COURT: And you want me to admit the reacted
7 version?

8 MS. WU: Yes, Your Honor. I believe that would be
9 appropriate given the sensitive nature of the document.

10 THE COURT: I will withdraw 00131 and substitute
11 00131-A.

12 MS. WU: Thank you, Your Honor.

13 BY MS. WU:

14 **Q.** Doctor, do you have the document in front of you?

15 **A.** Yes, I do.

16 **Q.** Thank you for your patience while we went through our
17 housekeeping.

18 I would like to call your attention to Box 3, which is
19 at the upper right-hand corner of the document, and that's
20 the date of the overdose which is March 5th, 2007. Do you
21 see that?

22 **A.** Yes, correct.

23 **Q.** Now, I would like to call your attention down to
24 Box 9-D, which is the county of death, and it reads Cabell.
25 Do you see that?

1 **A.** Yes.

2 **Q.** Did you say yes, Doctor? I'm sorry.

3 **A.** Yes, I do. Sorry. I said yes.

4 **Q.** Thank you. Now, I would like to ask you to look down
5 on the document to Box 27.

6 **A.** Yes.

7 **Q.** Part 1. And you'll see it says immediate cause. Do
8 you see that, Doctor?

9 **A.** Yes.

10 **Q.** And that's the cause of death information which feeds
11 into your analyses for the overdoses in Cabell County in
12 this case, correct?

13 **A.** Correct.

14 **Q.** Okay. In Box 29 it reads morphine intoxication,
15 correct?

16 **A.** Correct.

17 **Q.** And then further down in Part 2 it says manner of
18 death, accident. Do you see that?

19 **A.** Yes.

20 **Q.** And that's important because you only looked at
21 accidental deaths in connection with your work in this case,
22 correct?

23 **A.** All of this data is actually all drug overdose -- all
24 drugs involved, irregardless of whether -- that one
25 component that I looked at was accident, yes, that one.

1 Q. Okay. Doctor, because the immediate cause of death as
2 reflected in Box 27 is morphine intoxication, this is an
3 overdose death that the data you used to form your opinions
4 in this case attributes to prescription opioids, correct?

5 A. This is the way it would be coded, yes.

6 Q. And this is an overdose that occurred in 2007, which
7 falls during the time period when you opined that
8 heroin-related overdose deaths were very uncommon in West
9 Virginia, correct?

10 A. Correct. Yes.

11 Q. Doctor, you didn't review this death certificate in
12 connection with forming your opinions in this case, correct?

13 A. Yes.

14 Q. Now, I'd like to ask you to stick with me on this
15 document and look down to Box 30. And it's over on the
16 right register. Do you see that, Doctor?

17 A. Yes.

18 Q. And it says describe how injury occurred. Do you see
19 that?

20 A. Yes.

21 Q. And it reads injected illicit narcotic. Do you see
22 that, Doctor?

23 A. Yes.

24 Q. Okay. Now, I would like to show you another document
25 related to the same incident.

1 MS. WU: Your Honor, may I approach?

2 Your Honor, I identified for the record DEF-WV-01630.
3 This document also includes personal identifying information
4 and, with the Court's permission, as well as the permission
5 of counsel, I would like to replace it with a version that's
6 been redacted in order to protect the individual's identity.

7 THE COURT: All right. Do you want this admitted?

8 MS. WU: I will admit the redacted version with
9 the Court's permission.

10 THE COURT: Is there any objection to the
11 admission of the exhibit?

12 MR. FARRELL: I'm going to say yes. I'm going to
13 try to not make a smart comment here. Judge, we could tell
14 stories of individual overdose cases in Huntington-Cabell
15 County, West Virginia using death certificates and autopsies
16 for the next year and a half.

17 THE COURT: That's not what she's using it for.
18 You're using this as just an example of the type of
19 materials that are used to reflect the conclusions of the --
20 of the causes of death and so forth, aren't you?

21 MS. WU: Yes, Your Honor. I would use this in a
22 manner similar to the last document. I would note that
23 DEF-WV-01630 qualifies as a public record as it is a report
24 of death investigation and, therefore, is admissible on that
25 basis and I would not be using it for -- for anecdotal

1 evidence other than to test the reliability of the --

2 THE COURT: Is there a public record that's
3 available?

4 MS. WU: Yes, sir.

5 MR. FARRELL: I don't believe that toxicology
6 reports are available to the public but, again, Judge, I
7 understand the point she's trying to make. I don't know
8 that we need to use this man's toxicology report and death
9 certificate for her to make her general point.

10 THE COURT: Well, I'm going to cut the baby in
11 two. I'm not going to admit it into evidence, but I will
12 let you use it to question.

13 MS. WU: Thank you, Your Honor.

14 BY MS. WU:

15 Q. Doctor, do you have West Virginia -- DEF-WV-01630 in
16 front of you?

17 A. Yes, I do.

18 Q. All right. Now, I'd like to ask you to look at Page 1.

19 A. Yes.

20 Q. And you don't need to read the name aloud, but could
21 you confirm that the subject of this report is the same as
22 the subject of the death certificate we looked at in the
23 record as DEF-WV-131-A?

24 A. Has the same name, yes.

25 Q. Now, Doctor, I'd like to ask you to turn to Page 5 of

1 the report of death investigation and, just for ease, I'm
2 talking about the small numbers on the left side of the
3 document. Are you there, Doctor?

4 **A.** The small numbers to the left side of which document?

5 **Q.** DEF-WV-1630. It's the report --

6 **A.** Yes, exactly.

7 **Q.** Thank you, Doctor. Could I call your attention about
8 halfway down to the page to the section that reads opinion?
9 Do you see that?

10 **A.** Yes. Is this on the first page or further on in the
11 opinion?

12 **Q.** Doctor, I'm looking at the report of death
13 investigation identified as DEF-WV-1630 and I'm now looking
14 at Page 5 of the document.

15 **A.** Oh, Page 5? Because I thought that was the one, yes.

16 **Q.** Thank you, Doctor.

17 **A.** Yes. Opinion, yes.

18 **Q.** Now, under the opinion section it reads the presence of
19 a congener narcotic (codeine) suggests the possibility that
20 the original injected narcotic was heroin. Do you see that,
21 Doctor?

22 **A.** Yes.

23 **Q.** The Medical Examiner who conducted the Autopsy Report
24 as reflected in this document was of the opinion that the
25 individual who overdosed had ingested an illicit narcotic;

1 specifically, heroin, correct?

2 **A.** That's what he says. He says illicit narcotic, yep.

3 **Q.** According to your report and the data on which it
4 relies, this death event was categorized as a prescription
5 opioid overdose, correct?

6 **A.** Morphine was listed as the only thing on the death
7 certificate, so that would have been the case.

8 **Q.** Thank you, Doctor. We can put those aside.

9 Doctor, in forming your opinion that heroin was
10 relatively rare in Cabell County prior to 2011, you didn't
11 look at death certificates like the documents that we just
12 reviewed, correct?

13 **A.** No, I did not.

14 **Q.** You also didn't review any law enforcement materials
15 which might have referenced the prevalence of heroin in the
16 community, correct?

17 **A.** No, I did not.

18 **Q.** Now, Doctor, remaining focused on the time period 2001
19 through 2011, I would like to talk to you about the way you
20 categorized fentanyl-related deaths.

21 Doctor, you understand that fentanyl is available in
22 some prescription forms, correct?

23 **A.** Correct.

24 **Q.** You also understand that illicit fentanyl is available
25 to the community as a street drug, correct? Non-FDA

1 approved forms of fentanyl are available?

2 **A.** Yes.

3 **Q.** For purposes of the opinions that you have offered in
4 this case, you treated all overdoses related to fentanyl
5 that occurred prior to 2011 as prescription opioid-related
6 overdose events, correct?

7 **A.** It was 2013, I think, but yes.

8 **Q.** And could we -- just for easier, could we look at what
9 was Figure 2 to Dr. Smith's report and I'm again borrowing
10 plaintiffs' demonstrative. Thank you.

11 In fact, if we look at Figure 2 to your report, we see
12 that you first identified a fentanyl-related overdose in
13 Cabell County in 2014, correct?

14 **A.** We first identified an illicit -- what we considered to
15 be illicit. If you go back and look at my Exhibit A, there
16 were a few cases of fentanyl discovered earlier in this
17 county.

18 **Q.** And thank you for disciplining my language, Doctor.
19 You first identified an illicit fentanyl overdose death in
20 Cabell County in 2014, correct?

21 **A.** That's correct.

22 **Q.** Thank you, Doctor. Relying on just the cause of death
23 data that you looked at in this case, there's actually no
24 way to distinguish between prescription fentanyl and illicit
25 fentanyl, correct?

1 **A.** That's correct.

2 **Q.** In order to determine whether an overdose death was
3 related to prescription fentanyl or illicit fentanyl, you
4 would have to look at additional documents beyond the data
5 that you've used in this case, correct?

6 **A.** Yes.

7 **Q.** Doctor, you didn't look at those types of law
8 enforcement reports or death investigation records for
9 forming your opinions in this case, correct?

10 **A.** No, I did not.

11 **Q.** Doctor, however, you know that illicit fentanyl existed
12 prior to 2014, correct?

13 **A.** There were -- yes. You brought to my attention during
14 my deposition of a report that showed that across the
15 country in, I think, 2005 to 2007 there were -- there were
16 just over a thousand deaths across the whole country during
17 that period of time.

18 **Q.** You have a great memory, Doctor. Let me show you that
19 document now so we can look at it together.

20 **A.** That was across the whole country though.

21 MS. WU: Judge, may I approach?

22 THE COURT: Yes.

23 BY MS. WU:

24 **Q.** Doctor, I've handed you a document marked DEF-WV-1315,
25 which is a fentanyl briefing guide for first responders. Do

1 you see that?

2 **A.** Yes.

3 **Q.** This is a document that was created by the Drug
4 Enforcement Administration, correct?

5 **A.** Correct.

6 **Q.** You didn't review this document before preparing your
7 report and opinions in this case, correct?

8 **A.** I had not seen this specific document.

9 **Q.** Okay. Now, I'd like to ask you to turn with me to Page
10 4 of the document using the small numbers at the left-hand
11 corner. On the left side of the document, do you see
12 Section 1, history of fentanyl, Doctor?

13 **A.** Yes.

14 **Q.** And if I could cull your attention down to the bottom
15 paragraph in the left-hand column that reads between 2000
16 and 2005, U. S. law enforcement agencies identified and
17 dismantled several clandestine fentanyl laboratories located
18 throughout the United States. However, beginning in 2005,
19 law enforcement agencies in the Midwest and Northeast, from
20 Chicago to New Jersey, began noticing an alarming number of
21 overdose deaths in their respective areas. Between 2005 and
22 2007, approximately 1,013 fentanyl-related deaths in this
23 corridor were attributed to the lethal heroin/fentanyl
24 mixture. Do you see that, Doctor?

25 **A.** Yes.

1 **Q.** Doctor, you were not aware of the prevalence of illicit
2 fentanyl as early as 2000 to 2005 when you produced your
3 opinions in this case, correct?

4 **A.** I wasn't aware of it and then I looked at your results.
5 The interesting thing to me, because I -- I was not aware of
6 that, but then when I looked at it and did a little bit more
7 research myself, I found that during that period of time the
8 number of those deaths were less than 1% of all the deaths
9 in the U. S. If we had counted those thousand deaths, it
10 would be less than a thousand deaths in the entire country.
11 So, it really was a small part of the whole drug overdose
12 problem then.

13 **Q.** I'm happy to have inspired some research, Doctor, but
14 you didn't take that information into consideration in
15 forming your opinions for this case, correct?

16 **A.** No, I didn't, but I did notice that the number of
17 fentanyl overdoses during this time in West Virginia were
18 small. And in Cabell County, for example, there were less
19 than six, and most years were two or three, and that would
20 have been consistent with what I did know about the legal
21 prescription fentanyl, which was there was trouble with the
22 patches and people were dissolving the chemicals out of the
23 patches and using. So, there were some deaths involved in
24 that.

25 **Q.** You didn't consider any law enforcement reports from

1 Cabell County related to the availability of illicit
2 fentanyl in the community prior to 2014, correct?

3 **A.** No, I did not.

4 THE COURT: Ms. Wu, we need to take a break when
5 you get to a stopping point.

6 MS. WU: We can do it now, Judge. Thank you.

7 THE COURT: All right. Let's be in recess for ten
8 minutes.

9 Dr. Smith, you can step down during the break, if you
10 wish.

11 THE WITNESS: Thank you very much.

12 (Recess taken)

13 THE COURT: You may proceed.

14 MS. WU: Thank you, Your Honor.

15 BY MS. WU:

16 **Q.** Doctor, earlier today you discussed with
17 plaintiffs' counsel a 2008 article which was identified
18 as P-43566. Do you have a copy of that with you?

19 **A.** Yes, I do.

20 **Q.** Okay. This is the same copy of the 2008 article that
21 you discussed with Ms. Kearse during your examination this
22 afternoon; correct?

23 **A.** Yes, that's correct.

24 **Q.** Now, under "Design, Setting, and Participants" on Page
25 1, do you see that?

1 **A.** Yes.

2 **Q.** It says, "The study population was all state residents
3 who died of unintentional pharmaceutical overdoses in West
4 Virginia in 2006."

5 Do you see that, Doctor?

6 **A.** I do see that.

7 **Q.** So the study population here was pharmaceutical
8 overdoses as opposed to all overdoses as you testified
9 earlier; correct?

10 **A.** Yes, it's pharmaceutical -- by pharmaceutical they
11 would be meaning drug overdoses as against an overdose, an
12 overdose from some other cause.

13 **Q.** Doctor, are you aware that the number of overdoses
14 cited in this article is significantly less than the West
15 Virginia overdose data for all drugs for that same year,
16 2006?

17 **A.** I actually hadn't worked up the numbers, but I'm not
18 surprised because they would be working on provisional data
19 that was only a little bit -- all the cases might not have
20 been settled. And, also, they restrict themselves to
21 residents of the state which could also explain that.

22 **Q.** So, Doctor, you understand that there were more overall
23 drug poisoning deaths in West Virginia in 2006 than were
24 studied in this 2008 article that you testified about
25 earlier today; correct?

1 **A.** That's correct.

2 **Q.** Now, I'd like to call your attention to Page 7 of the
3 article, actually the very end, the last sentence of Page 6
4 which carries over to Page 7. Are you there, Doctor?

5 **A.** Yes, I see that.

6 **Q.** Okay. It reads, "Those with a history of abusing
7 prescription drugs report beginning use of psychotherapeutic
8 drugs as a way to moderate the effects of street drugs and
9 beginning use of prescription opioids as a substitute when
10 street drugs are not available."

11 Do you see that, Doctor?

12 **A.** Yes.

13 **Q.** Do you have any, any reason to disagree with that
14 statement?

15 **A.** I think they're talking about -- they talk -- I'm not
16 sure what they're meaning by psychotherapeutic. I must say
17 I'm not -- I, I can read the -- see the statement. But I'm
18 not sure about how they define psychotherapeutic.

19 **Q.** This is an article that you find credible; correct?

20 **A.** Overall, yes, yes. I do read articles and I don't
21 always agree with every single word in an article.

22 **Q.** And this is an article that you've cited in your
23 report; correct?

24 **A.** Yes.

25 **Q.** Now, I'd like to ask you to continue reading on Page 7.

1 If we go to the center column, the first full paragraph, it
2 says, "This study did not examine the sources of the
3 involved opioids."

4 Do you see that, Doctor?

5 **A.** I do and I'm not surprised because it's the same thing
6 as the molecules that were found on testing.

7 **Q.** Okay. Then it continues. "However, the majority of
8 persons using prescription pain relievers for non-medical
9 indications report receiving their drugs for free from a
10 friend or relative. Among these, the majority report that
11 the friend or relative received the drug from a single
12 clinician."

13 Do you see that, Doctor?

14 **A.** I do see that, but that wasn't from their findings.
15 That is a reference they referred to -- another study that
16 found that, not in this study.

17 **Q.** That's right. It does provide a citation to another
18 epidemiological article; correct?

19 **A.** That's correct. It's the study done 19 -- oh, this is
20 from a study of across the state -- yes, across the country.

21 **Q.** And you have no reason to dispute the findings as set
22 forth here on Page 7; correct?

23 **A.** No. I haven't read the report, but I, I trust that
24 these people read the report and interpreted it correctly.

25 **Q.** Thank you, Doctor. We can set that aside.

1 With Ms. Kearse you also talked about another report,
2 the 2016 West Virginia Overdose Fatality Analysis Report
3 which was identified as Plaintiffs' Exhibit 44211.

4 Do you have that document, Doctor?

5 **A.** Yes, I do.

6 **Q.** Doctor, in connection with your testimony on this
7 report, you testified that 91 percent of all West Virginia
8 decedents had a documented history of controlled substance
9 prescriptions within the PDMP for West Virginia; correct?

10 **A.** That's what the article said and I quoted that.

11 **Q.** Doctor, you don't know what percentage of West
12 Virginians have ever been prescribed a controlled substance;
13 correct?

14 **A.** No, I do not know what percent -- no, I do not.

15 **Q.** Do you know if it's consistent with the rate of
16 91 percent?

17 **A.** I, I do not know that. I have not -- I haven't looked
18 at the data for that.

19 **Q.** You don't know one way or another if the rate of
20 controlled substance prescriptions is the same, higher, or
21 lower in the general population as compared to those who
22 overdosed; correct?

23 **A.** No, I haven't. And, in fact, as a good epidemiologist,
24 that's something I'll go and check on in another day.

25 **Q.** Thank you, Doctor. As you sit here today, you don't

1 know that?

2 **A.** No.

3 **Q.** Doctor, pharmacies can lawfully dispense an opioid
4 medication only with a prescription from a doctor or other
5 prescriber; correct?

6 **A.** That's the way I understand the rules.

7 **Q.** And every one of the decedents that you referenced in
8 connection with this 2016 report had a prescription that was
9 filled pursuant to a script from a doctor; correct?

10 **A.** That -- that's the way that -- that's how the
11 information gets into the PDMP.

12 **Q.** Okay. Now, I'd like to look at just a few aspects of
13 this report. I'd like to ask you to turn to Page 13, if you
14 would.

15 Now, at the top of Page 13 you see Section 2.3.2
16 Polypharmacy. Do you see that, Doctor?

17 **A.** On Page 13?

18 **Q.** It's Page 10 of the report and it's Page 13 in the
19 small number at the very right-hand bottom.

20 **A.** Page 10 of the report. Are the numbers that are on
21 here --

22 **Q.** It's the very --

23 **A.** I'm looking at Page 10 at the bottom. Yes, I see it.
24 Yes, I've got that.

25 **Q.** I'm sorry for the confusion, Doctor. We have many

1 numbers. There's a section titled "Polypharmacy." If I
2 could call your attention to the third sentence, it reads,
3 "Increasingly, polypharmacy (the use of multiple drugs) is
4 observed among overdose decedents in West Virginia. The
5 average number of drugs involved in fatal overdoses has
6 increased from 2.3 drugs per fatal overdose in 2001 to three
7 drugs per fatal overdose in 2015."

8 Do you see that, Doctor?

9 **A.** I do see that.

10 **Q.** You don't have any basis to disagree with this
11 statistic on polypharmacy; correct?

12 **A.** No.

13 **Q.** And then it continues, "Among the 830 West Virginians
14 included in this report who died from overdose in 2016,
15 86 percent had multiple drugs in their system at the time of
16 death."

17 Do you see that, Doctor?

18 **A.** I do.

19 **Q.** Assuming a decedent was taking an opioid medication at
20 the time of death, you would expect that to show up in the
21 toxicology report; correct?

22 **A.** If it was taken recently enough that it hadn't been
23 metabolized, yes.

24 **Q.** It would show up in the toxicology report even if the
25 decedent was taking the opioid medication exactly as

1 directed by his or her doctor; correct?

2 **A.** That's correct. But the other thing is when the
3 medical examiner looks at the toxicology report, he looks at
4 the level of the drug. And if the level of the drug was
5 very incredibly low, he may not include that as being
6 responsible for the drug, for the death.

7 **Q.** Well, Doctor, just because a prescription opioid shows
8 up in a toxicology report, it doesn't mean that the
9 prescription drug caused the overdose; correct?

10 **A.** It would depend. If it was in Part 1 of the death
11 certificate in the opinion of the medical examiner, he
12 believes that it was part of the causal chain because what
13 happens with opioids, if you've had a prescription, even if
14 you had a normal level, a therapeutic level of an opioid
15 drug and then you added another opioid drug that maybe in
16 itself was not enough to kill, but the two of them together
17 may be enough to suppress the respiration so that you would
18 die.

19 **Q.** Doctor, the data reported in this 2016 report is not
20 limited to overdoses that were caused by prescription
21 opioids; correct?

22 **A.** It contains reports of all of the ones, yes.

23 **Q.** And, so, it includes overdoses where a prescription
24 opioid was a contributing factor; correct?

25 **A.** Well, in the ones where they consider opioids involved,

1 they consider it a contributing factor. But if there was --
2 if it was a particular drug overdose that did not involve
3 any opioid at all, then obviously it's not there.

4 **Q.** Doctor, you don't know how many of the decedents
5 referenced in this 2016 report filled an opioid prescription
6 within 30 days of the death experienced an overdose which
7 was caused by that prescription medication; correct?

8 **A.** They do list in the report the number of the decedents
9 that had a prescription in the 30 days.

10 **Q.** It does list that information. But my question was
11 just a little bit different. You don't know how many of the
12 decedents who had that prescription filled within 30 days of
13 death had their death which was caused by the prescription
14 opioid medication; correct?

15 **A.** I'm not 100 percent sure, but that, that could be the
16 case because I think they -- if I remember correctly, they
17 include all overdose -- what you're telling me is they are
18 recording all overdose deaths. And, so, some of them might
19 not be due to opioids.

20 **Q.** That's not something that you're -- you can testify to
21 based on your knowledge; correct?

22 **A.** No.

23 **Q.** Thank you, Doctor.

24 **A.** I didn't have all the details of that report.

25 **Q.** Okay. So I'd like to turn to another article.

1 MS. WU: Could I get MC-West Virginia-1229.

2 Your Honor, may I approach?

3 BY MS. WU:

4 Q. Doctor, I've handed you an article which is titled
5 "Changing Dynamics of the Drug Overdose Epidemic in the
6 United States from 1979 through 2016." It's identified
7 as MC-West Virginia-1229.

8 Do you see that, Doctor?

9 A. Yes, I do.

10 Q. This article was published in the Journal of Science.
11 Do you see that?

12 A. Yes.

13 Q. Science is published by the American Association for
14 the Advancement of Science; correct?

15 A. Correct.

16 Q. Are you familiar with this publication?

17 A. I, I looked at it a long time ago, but I really can't
18 at all much remember the content of it.

19 Q. You testified earlier today that you're interested in
20 overdose trends; correct?

21 A. Yes.

22 Q. And this is an article that relates to overdose trends?

23 A. No, no. As I say, I've got it in my collection and I
24 do remember it, but it's been a little while since I've read
25 it.

1 **Q.** You have a large collection. So I'd like to call your
2 attention to Footnote 5 which identifies one of the
3 co-authors of this article. Dr. Kun Zhang is identified as
4 an employee of the CDC's Division of Unintentional Injury
5 Prevention. Do you see that?

6 **A.** Yes, I see that.

7 **Q.** And, so, you consider this to be a reliable article
8 authored by reliable experts in the field of epidemiology;
9 correct?

10 **A.** I would say that this includes people -- it includes,
11 you know, obviously scientists but I don't necessarily --
12 and to be frank with you, it's been a while since I've
13 looked at this. And most articles I look at I have some
14 issues with, but only after a long period of study of it.
15 And if I had known about this beforehand, I might have done
16 some preparation and done some work on it.

17 **Q.** Fair enough. So let's see what we can do with it.

18 So in the second column of the first page -- and I'm
19 going to point you to the conclusion section. Do you see
20 that, Doctor?

21 **A.** On this page that's being shown?

22 **Q.** Yes, on Page 1. I'm sorry, the results section in the
23 middle column. Sorry about that. Are you with me, Doctor?

24 It says, "The overall mortality rate for unintentional
25 drug poisonings in the United States grew exponentially from

1 1979 through 2016."

2 Do you see that, Doctor?

3 **A.** So this is on the first page of the article?

4 **Q.** Yes, on the page -- Page 1 of 1 of the summary of the
5 article.

6 **A.** Oh, I see. So you've cut and paste and made a summary.
7 Yes, I see what you've done, yes. I was looking at the
8 original article. I can see that, yes.

9 **Q.** Doctor, then it continues. Are you reading with me
10 now? I'm sorry. I want to make sure we're together.

11 **A.** Yes, I am.

12 **Q.** Thank you. It says this -- the -- I'm sorry. The
13 exponential growth that the authors describe is then
14 reflected on the next page. So if we can turn to Page 2 of
15 the document -- are you with me, Doctor?

16 **A.** Do you want me to turn to Page 2 with the A and B,
17 individual drugs and all drugs?

18 **Q.** Yes, Doctor.

19 **A.** Yes.

20 **Q.** And, now, if I can call your attention to Chart B which
21 is all drugs. Do you see that?

22 **A.** Yes.

23 **Q.** It says the exponential growth that was referenced by
24 the authors is reflected in the graph on the right-hand side
25 of the page. Do you see that, Doctor?

1 **A.** Yes.

2 **Q.** According to this graph, the national average mortality
3 rate per 100,000 people was below four through at least the
4 year 1998. Do you see that, Doctor?

5 **A.** Yes.

6 **Q.** That rate, less than four per 100,000, is consistent
7 with what you found in the West Virginia data which you
8 obtained from the CDC for the period 1979 through 2000;
9 correct?

10 **A.** Yes. Actually, if I was to look at the 2000 one, that
11 is not consistent. The data that we got from the Centers
12 for Disease Control, the data is very flat if you look at my
13 graph. It's so flat, you can almost not see a rise in it.

14 **Q.** Well, so, so, let's look at your data. Doctor, do you
15 have a copy of your report for reference?

16 **A.** Yes, I do.

17 **Q.** Okay.

18 MS. WU: And, Mr. Reynolds, could we put that up
19 for reference of the Court?

20 BY MS. WU:

21 **Q.** Doctor, I can hopefully move us through this, if I
22 could call you to Page 14 of your report.

23 And, actually, in the text of the report under -- it
24 says, "This shows that for West Virginia the age adjusted
25 drug poisoning rates which are mostly due to drugs had

1 fairly stable and very low rates from 1979 until 1999-2000
2 which were all under four per 100,000 population."

3 Do you see that, Doctor?

4 **A.** Yes. So they're a low rate. So we didn't see the
5 increase. You're asking me to look at all drugs for -- in
6 this graph, and we didn't see that increase.

7 **Q.** So for the period up through 1998 in the national data
8 and the West Virginia data, the rate of poisoning was less
9 than four per 100,000; correct?

10 **A.** Yes.

11 **Q.** Okay. So, now, if we can turn back to the Jalal
12 article that we were looking at, and if I can call your
13 attention to Page 4 of that article. And I'm using the
14 small numbers, so it's Page 3 of 6 of the article, or
15 MC-West Virginia-1229 at Page 4.

16 Do you see that, Doctor?

17 **A.** I'm on Page 3 of 6.

18 **Q.** Okay, great. So in the left-hand column if we go to
19 the third full paragraph, it reads, "Mortality curves from
20 individual drugs do not show regular or predictable growth
21 patterns. Nonetheless, we observed that the annual sum of
22 all drug overdose mortality rates follows a remarkably
23 smooth mathematical trajectory."

24 Do you see that, Doctor?

25 **A.** I do see that.

1 Q. Doctor, --

2 A. That does not -- is not what was happening in West
3 Virginia.

4 Q. We'll get there.

5 Doctor, you understand that the smooth trajectory the
6 authors describe is the exponential growth curve shown in
7 the graph that we just discussed --

8 A. Yes.

9 Q. -- which was on Page 2 of the document; correct?

10 A. Yes.

11 Q. Now, Doctor, you've offered the opinion that the drugs
12 primarily responsible for the fatal overdoses in Cabell
13 County changed over time; correct?

14 A. Yes.

15 Q. You didn't consider whether the fatal overdose rate in
16 Cabell County follows an exponential curve similar to that
17 graph in the Jalal article; correct?

18 A. It -- it's -- the West Virginia curve would follow that
19 at a much later period.

20 Q. But you didn't try to fit your data from Cabell County
21 to an exponential curve like that graph in the Jalal
22 article; correct?

23 A. No, I didn't.

24 Q. Now, if we could stick on the Jalal article and now
25 turn to Page 6 in the numbering on the left-hand side, or

1 Page 5 of 6 of the article. Are you with me, Doctor?

2 **A.** Page 5 of 6, yes.

3 **Q.** Yes. Okay. So I'd like to call your attention to the
4 middle column with the heading "The opioid crisis may be
5 part of a larger, longer-term process."

6 Do you see that?

7 **A.** Yes.

8 **Q.** The authors write, "The epidemic of drug overdoses in
9 the United States has been inexorably tracking along an
10 exponential growth curve since at least 1979, well before
11 the surge in opioid prescribing in the mid 1990s. Although
12 there have been transient periods of minor acceleration or
13 deceleration, the overall drug overdose mortality rate has
14 regularly returned to the exponential growth curve. This
15 historical pattern of predictable growth for at least 38
16 years strongly suggests that the epidemic will continue
17 along this path for several more years."

18 Do you see that, Doctor?

19 **A.** I do see that.

20 **Q.** You didn't, again, try to fit your data for Cabell
21 County against the exponential curve for overdose rates
22 nationally; correct?

23 **A.** No, I did not because if you look at my curves, we had
24 no evidence of an exponential curve from 1980 to 2000 for
25 the state when the figures were so low.

1 So what to me is most important is that West Virginia
2 didn't have this increasing drug problem until 2000. And we
3 didn't show the exponential increase beforehand. So we were
4 different.

5 To me, what's so key is that West Virginia was
6 different to the national trends that was going on in some
7 of the cities of the country and stuff like that.

8 **Q.** But, in fact, Doctor, as you testified just a short
9 while ago, the rate of exponential drug poisonings, both in
10 Cabell County and nationally, were both less than four per
11 100,000 up through -- for the years 1979 through 1998.

12 Correct?

13 **A.** That was the rates for the state, not for Cabell
14 County.

15 **Q.** I apologize. Yes, that was the state data.

16 **A.** Yes. So there was no evidence in the state that there
17 was any exponential increase, whereas at the national level
18 he shows an exponential increase which suggests to me that
19 we didn't have an underlying drug problem, and then suddenly
20 there began to be an underlying drug problem.

21 **Q.** But that's not work that you've done in this case;
22 correct?

23 **A.** No. I'm just looking at what you've given me to
24 interpret, and also looking at my graph and thinking, well,
25 how does that compare.

1 Q. It's not work that you've done in this case; correct?

2 A. No.

3 Q. So I'd like to ask you just a few more questions about
4 recent overdose trends which are identified in your report,
5 specifically Exhibit A.

6 MS. WU: Could we, Mr. Reynolds, pull up from the
7 plaintiffs' demonstrative Exhibit A which is -- I think it's
8 slide 9. Yes. Thank you.

9 BY MS. WU:

10 Q. Doctor, this is Exhibit A to your report which you
11 testified about just a short while ago with plaintiffs'
12 counsel; correct?

13 A. That's correct.

14 Q. The data in Exhibit A was provided to you by the West
15 Virginia Vital Statistics Office; correct?

16 A. Yes. The experts in their office presented it to me,
17 yes.

18 Q. Exhibit A identifies 251 overdoses associated with
19 cocaine in the 18-year period between 2001 and 2018. Do you
20 see that, Doctor?

21 A. Yes.

22 Q. And 171 of those cocaine deaths occurred in the years
23 2012 through 2018. Do you see that, Doctor?

24 A. Oh, yes, yes. It's on the next page, yes.

25 Q. Doctor, if it's easier, I think you have a copy of your

1 report up there if it's easier for you to look at Exhibit A
2 as well.

3 **A.** Yes.

4 **Q.** Okay. I'll wait for you to get the paper.

5 **A.** Yes, I've got it.

6 **Q.** Okay. So are you at Exhibit A, Doctor?

7 **A.** Yes.

8 **Q.** Okay. So Exhibit A also includes a column identifying
9 the number of fatal overdoses associated with
10 methamphetamine. Do you see that?

11 **A.** Yes.

12 **Q.** And your Exhibit A identifies 129 fatal overdoses
13 associated with methamphetamine in Cabell County between
14 2001 and 2018; correct?

15 **A.** Correct.

16 **Q.** 127 of those fatal overdoses occurred just between 2012
17 and 2018; correct?

18 **A.** Correct.

19 **Q.** And nearly half of those meth overdoses occurred just
20 in 2018, 59 of them; correct?

21 **A.** That's correct.

22 **Q.** This data indicates that there's been a significant
23 increase in the rate of methamphetamine overdoses since
24 2012; correct?

25 **A.** Yes, there have, but you have to remember with the

1 poly -- even with the meth there, it's largely poly
2 substances. So there are other drugs being found with them.

3 **Q.** Because polypharmacy is so common in the overdose
4 deaths in Cabell County; correct?

5 **A.** Yes.

6 **Q.** Now, the last column of your Exhibit A shows eight
7 fatal overdoses associated with U-47700. Do you see that,
8 Doctor?

9 **A.** Yes.

10 **Q.** And all of those deaths occurred between 2016 and 2018.
11 Do you see that, Doctor?

12 **A.** Yes.

13 **Q.** U-47700 is an illicit opioid which is commonly referred
14 to as pink heroin; correct?

15 **A.** Correct.

16 **Q.** So, Doctor, having gone through this, during the course
17 of your testimony today we've discussed five drugs that are
18 always illicit, or which are most of the time sold in an
19 illicit form; is that right? Those are heroin, illicit
20 fentanyl, cocaine, methamphetamine, and pink heroin;
21 correct?

22 **A.** Correct.

23 **Q.** According to Exhibit A of your report, 1,151 fatal
24 overdoses were reported in Cabell County over the 18-year
25 period 2001 to 2018; correct?

1 **A.** Yes.

2 **Q.** More than half of those fatal overdoses, 657 of them,
3 were reported in the four-year period between 2014 and 2018;
4 --

5 **A.** That is correct.

6 **Q.** -- correct?

7 **A.** Yes. I haven't done the math but, yes, that's correct
8 I'll assume.

9 **Q.** Some of my friends over there have a calculator if we
10 need it.

11 Okay. So, Doctor, heroin accounted for at least half
12 of all fatal overdoses in Cabell County in the years 2013,
13 2014, and 2015; correct?

14 **A.** If your math is correct, but that order of magnitude.

15 **Q.** Okay. Even after the emergence of illicit fentanyl
16 around 2014, based on your data, heroin accounted for
17 approximately one-third of fatal overdoses in 2016, 2017,
18 and 2018; correct?

19 **A.** That, that -- yes, I assume so.

20 **Q.** And illicit fentanyl accounted for at least half of all
21 fatal overdoses in Cabell County in the years 2016, 2017,
22 and 2018; correct?

23 **A.** Yes. It was found in -- it was found in those, yes.
24 It doesn't mean it's responsible on its own.

25 **Q.** Okay. Doctor, distributors, the defendants in this

1 case, McKesson, Cardinal, and ABDC, don't sell illicit
2 opioids like heroin or illicit fentanyl; correct?

3 **A.** Not to my knowledge.

4 **Q.** And they don't sell cocaine or methamphetamine;
5 correct?

6 **A.** I, I don't know. You'll have to check with them
7 whether they sell cocaine because cocaine is used by some
8 oral surgeons to anesthetize the nose for endoscopies and
9 stuff like that. So you may want to check with them whether
10 they sell cocaine because they may do.

11 **Q.** In the, the illicit form just as identified in Exhibit
12 A --

13 **A.** Yeah. We've only been looking at the molecules.

14 **Q.** Correct, okay. So, Doctor, the data that you relied on
15 in your report reflects that there has been a decline in
16 fatal overdoses in Cabell County between 2017 and 2018;
17 correct?

18 **A.** Yes.

19 **Q.** And we see that here in your chart. In 2017 there were
20 202 drug overdose deaths; correct?

21 **A.** Yes.

22 **Q.** And in 2018 there were 149 drug overdose deaths;
23 correct?

24 **A.** Correct.

25 **Q.** And that -- and between 2017 and 2018 that change is

1 about a one-quarter decline in the rate of drug overdose
2 deaths; correct?

3 **A.** That's correct.

4 **Q.** And if we look just at opioid related overdoses, the
5 decline during that same period, 2017 to 2018, is even
6 greater going from 184 in 2017 to 134 in 2018; correct?

7 **A.** Yes. But interesting when we see a trend, we always
8 like to go back and, as I say, I continue to do my research.
9 And we're -- according to the, a recent article using this
10 same data that I haven't got yet, they found a dramatic
11 increase in the last year. So it hasn't continued to
12 decline.

13 **Q.** Well, Doctor, just looking at 2017 to 2018 in Cabell
14 County, we see a decline in opioid related overdoses of
15 approximately one-third; correct?

16 **A.** Correct.

17 **Q.** Now, you just mentioned that you're interested in
18 trends, and perhaps the trend line has changed in Cabell
19 County since 2018. Is that, is that what you're
20 referencing?

21 **A.** I, I would want to see more years of data. And that's
22 what carries on over time to see if there's a trend because
23 if you look at all of the slides that I've produced, you see
24 ups and downs, ups and downs even if there was a, even if --
25 we're talking about small numbers here in small places. You

1 get a lot of variation even if at the state level there was
2 a broad trend. So I do not -- so that would be I would say
3 insufficient data to establish a trend.

4 **Q.** The Court has been able to hear about more recent data
5 and that decline from some other witnesses. That's not
6 something that you've studied in order to offer opinions in
7 this case; correct?

8 **A.** I don't have it here, no.

9 **Q.** Okay. Thank you, Doctor. I have no further questions
10 at this time.

11 THE COURT: Do either of the other defendants want
12 to cross?

13 Mr. Ruby?

14 MR. RUBY: Judge, I just have one document that I
15 wanted to look at with the witness with the permission of
16 the Court.

17 Mr. Reynolds, if you don't mind, could you pull up the
18 chart that you were just on, the Exhibit A to the report?

19 CROSS EXAMINATION

20 BY MR. RUBY:

21 **Q.** And, Dr. Smith, my name is Steve Ruby. I'm here
22 representing Cardinal Health.

23 You were just testifying about this Exhibit A to your
24 expert report; is that correct?

25 **A.** That's correct.

1 **Q.** And this is the chart that reflects the, the
2 information about the drugs that were found in the systems
3 of overdose decedents from 2001 through 2018 in Cabell
4 County; is that right?

5 **A.** Correct.

6 **Q.** And there were 1,151 total drug overdose deaths in that
7 period of time; correct?

8 **A.** Correct.

9 **Q.** And there were a little over 1,000, 1,002 of those in
10 which some opioid was found in the system of the decedent?

11 **A.** Correct.

12 **Q.** If you go to the portion of the chart on the next page
13 that Ms. Wu was just walking you through, she touched on the
14 numbers from some of the non-opioid drugs that were found in
15 the systems of decedents, including cocaine and
16 methamphetamine.

17 There were a few of the other numbers on this chart
18 that caught my eye. I just wanted to ask you very quickly
19 about those.

20 Do you see the column for Alprazolam?

21 **A.** Oh, yes.

22 **Q.** And in the period from '01 to 2018 that you looked at
23 here, there were 219 cases --

24 **A.** Correct.

25 **Q.** -- in which Alprazolam was found in the decedent's

1 system?

2 **A.** Yes.

3 **Q.** Now, Alprazolam is not an opioid; correct?

4 **A.** No. That's correct.

5 **Q.** Do you see the column for Diazepam?

6 **A.** Yes, I do.

7 **Q.** And according to the last row of the chart that you
8 have here from your report, there were 161 cases --

9 **A.** That's correct.

10 **Q.** -- in which Diazepam was found in the decedent's system
11 in the period of time you looked at; is that right?

12 **A.** Yes.

13 **Q.** And Diazepam is also not an opioid; correct?

14 **A.** No.

15 **Q.** Alprazolam is commonly known as Xanax; is that right?

16 **A.** Yes.

17 **Q.** Diazepam is commonly known as Valium; is that right?

18 **A.** Yes.

19 **Q.** Do you see the column next -- between those two for
20 Clonazepam?

21 **A.** Yes.

22 **Q.** According to the box at the bottom of that column,
23 there were 60 cases in which Clonazepam was found in a
24 decedent's system in this time period; is that right?

25 **A.** Correct.

1 Q. Clonazepam is not an opioid; correct?

2 A. Correct.

3 Q. Do you see the column for Gabapentin?

4 A. Yes.

5 Q. And according to the information in that column, there
6 were 48 cases in which Gabapentin was found in a decedent's
7 system in the time period that you looked at; correct?

8 A. Correct.

9 Q. Gabapentin is not an opioid; correct?

10 A. Correct.

11 Q. Further over to the right do you see the column for
12 Citalopram?

13 A. Yes.

14 Q. In the bottom of that column it indicates that there
15 were 45 cases in this period of time in which decedents had
16 Citalopram in their system; correct?

17 A. Correct.

18 Q. Citalopram is not an opioid; correct?

19 A. Correct.

20 Q. And then the column to the left of that for -- and I'm
21 going to mispronounce this -- Amitriptyline?

22 A. Yes.

23 Q. And at the bottom of that column do you see that 30
24 cases in this period of time the decedent had Amitriptyline
25 in their system?

1 **A.** Correct.

2 **Q.** Amitriptyline is not an opioid; correct?

3 **A.** Yes.

4 MR. RUBY: That's all I have, Your Honor.

5 THE COURT: Does AmerisourceBergen have anything?

6 MS. CALLAS: No questions, Your Honor.

7 THE COURT: Ms. Kearse, do you have any redirect?

8 MS. KEARSE: I do. I think Mr. Farrell would like
9 to ask a couple questions and then I'll finish it up.

10 REDIRECT EXAMINATION

11 BY MR. FARRELL:

12 **Q.** Good afternoon, Doctor.

13 **A.** Good afternoon.

14 **Q.** Yeah, the dynamic duo. I'll be tagged like they do in
15 wrestling.

16 I just want to ask you a couple questions about the
17 article that was shown. It's MC-WV-1229. This is the Jalal
18 article. Do you recall it?

19 **A.** Yes, I do.

20 **Q.** I think that in general --

21 MR. FARRELL: Judge, may I approach?

22 THE COURT: Yes.

23 BY MR. FARRELL:

24 **Q.** I think in general the question was whether or not
25 this article is demonstrating a historical pattern.

1 If we go over on the front page down to the conclusions
2 down here where -- right in the middle, this process --
3 "This historical pattern of predictable growth for at least
4 38 years suggests that the current opioid epidemic may be a
5 more recent manifestation."

6 Do you see that sentence there?

7 **A.** Yes, I do.

8 **Q.** Now, I want you to peek over here at the bottom
9 left-hand corner at the -- what do you call this kind of
10 chart in epidemiology terms?

11 **A.** It's a curve and it has an exponential shape.

12 **Q.** Yeah. It looks like there's a trend over time;
13 correct?

14 **A.** Correct.

15 **Q.** Now, this is -- is this particular drug trend, is it
16 for all drugs or is it for a specific drug? Do you know?

17 **A.** He's looking here at all drugs as a group.

18 **Q.** Yeah. Now this paper, does it also look at what it
19 calls sub -- I think there's a special word they use here.
20 It also looks at drugs independently.

21 Let's go to the next page, please.

22 **A.** Yes, it does.

23 **Q.** And if you go to the next page, do you see down here
24 individual drugs?

25 MR. FARRELL: Can you bring that up. Back up.

1 Yep. Can you blow up A?

2 BY MR. FARRELL:

3 **Q.** The actual trends over time for all drugs may
4 combine together, but there's -- this article actually
5 broke it out by sub topic, did it not?

6 **A.** Exactly, yes.

7 **Q.** Now, if you'll go to the same page, the bottom
8 right-hand corner of the third column, you'll see here
9 there's actually --

10 Don't blow it up. Don't do anything to it yet.

11 The paragraph starting "Since 2010."

12 **A.** Yes.

13 **Q.** This is a paragraph that is talking about the fact that
14 prescription opioid overdoses began to decline after 2012.
15 But what increased?

16 **A.** The fentanyl, the other opioids.

17 **Q.** Now, does this article also suggest why there was such
18 an inverse relationship between prescription drug overdose
19 declining and heroin, fentanyl increasing?

20 **A.** Not that I can --

21 MS. WU: Your Honor, --

22 THE COURT: Yes.

23 MS. WU: Objection, beyond the scope and this
24 witness has not offered any expert opinions as to causation
25 of the relationship between drugs.

1 THE COURT: Well, I think he did touch on this,
2 didn't he, Mr. Farrell?

3 MR. FARRELL: Yes, Your Honor. It's their article
4 they introduced.

5 THE COURT: Overruled. I'll allow it.

6 BY MR. FARRELL:

7 Q. So when you look on this column, what it actually
8 suggests is there's a number of factors why prescription
9 opioid overdose have decreased. And one of them is the
10 reformulation of Oxycontin in 2010. Are you familiar
11 with that?

12 A. Yes, I am.

13 Q. And the implementation of pain clinic laws, mandatory
14 PDMPs. Are you familiar with those?

15 A. Exactly.

16 Q. And then it goes on to the next page and says a
17 reduction in the amount of opioids prescribed. Are you, are
18 you familiar with the decline of prescription opioids being
19 prescribed by doctors?

20 A. That's what's described in the literature and included
21 here.

22 THE COURT: Just a minute. Mr. Ruby.

23 MR. RUBY: Your Honor, notwithstanding that it may
24 have been a statement in an article that I think the witness
25 was cross-examined about, he still hasn't been qualified to

1 offer any opinions here on the gateway theory. He's not
2 a -- he's not a specialist in addiction science. He's not a
3 psychiatrist.

4 So eliciting an opinion from him on whether this
5 article is correct or valid in any way when it, when it
6 speaks to the gateway theory opinions, the issues that Mr.
7 Farrell is trying to elicit, is beyond his qualifications
8 and certainly beyond the scope of the cross.

9 THE COURT: All he asked him was: Are you
10 familiar with the decline of prescription opioids being
11 prescribed by doctors? Overruled.

12 Can you answer that, Doctor?

13 THE WITNESS: Yes. I am aware of that. And also
14 I'm seeing -- reading what's in here reminded me what was in
15 it.

16 BY MR. FARRELL:

17 **Q.** Yes. And reading this, does it also remind you
18 that the rescheduling of hydrocodone compounds in 2014
19 reduced the decline of prescription opioid overdoses?

20 **A.** Yes, I'm very well aware of that literature.

21 **Q.** Now, it also suggests in this article that there's a
22 correlation, an inverse relationship in heroin overdoses,
23 does it not?

24 **A.** It does, yes.

25 **Q.** It calls it illicit opioids. And it goes on and it

1 talks and says here that sometimes these changes have
2 reduced overall deaths from the prescription opioids, but it
3 says it's possible they have made -- led to a sequelae or
4 a -- it's led to another cause or it's evolved, has it not?

5 **A.** It has.

6 **Q.** And this article goes through and it talks about
7 opioid-dependent persons switch to illicit opioids such as
8 heroin and fentanyl. And it actually identifies other
9 factors, does it not?

10 **A.** That's, that's what I understand, yes.

11 **Q.** It says the economic factors --

12 MR. RUBY: Your Honor, --

13 THE COURT: Just a minute, Mr. Farrell.

14 Mr. Ruby.

15 MR. RUBY: Your Honor, at this point, Mr. Farrell
16 is simply reading this article into the record.

17 THE COURT: I agree. I agree.

18 MR. FARRELL: I'll make my point a little more
19 succinct, Judge.

20 THE COURT: Ask him a question, Mr. Farrell.

21 MR. FARRELL: Yes, sir.

22 BY MR. FARRELL:

23 **Q.** All right. Take this one away here for a second,
24 the block away.

25 It took me a second to understand what these pictures

1 were here. But I want to see if I can point to something
2 else and make the illustration of the timing of the
3 prescription opioid epidemic.

4 You'll see here at the top, across the top it has
5 different categories: Total, male, female, white, black,
6 other, urban and rural. Do you see that, sir?

7 **A.** Yes, I do.

8 **Q.** All right. I'm going to focus on rural, but I'm going
9 to drop down. So take this away, please, for a second.

10 Now, if you look down the -- I always get it wrong --
11 the Y axis, it's overall, heroin, prescription opioids,
12 methadone. It has all the different drugs.

13 What I'd like to do is I'd like to take on this grid
14 and go rural, which is the last column, and drop down to the
15 row of prescription opioids. Yep, right there.

16 Now, this appears to be some type of scatter plot that
17 goes from left to right starting at about 2001; correct?

18 MS. WU: Your Honor, again, Mr. Farrell is simply
19 characterizing a document which is not in evidence.

20 THE COURT: You're testifying, Mr. Farrell. You
21 need to ask him questions.

22 BY MR. FARRELL:

23 **Q.** When you look at this particular grid that I've
24 shown you, what does it tell you on the distribution of
25 prescription opioids from 2001 to the present in rural

1 America?

2 **A.** What, what it does is it confirms my understanding as
3 to that there are two very different problems between the
4 rural areas and the, and the urban areas, or the country as
5 a whole, and that the rural -- and it was only until very
6 recently the Federal Government has even recognized that the
7 rural drug problem is so different from the, from the
8 classic sort of urban drug problem in New York and Detroit
9 and places like that, and that the entire -- the -- most of
10 the urban drug use had initiated with prescription, with
11 prescription opioids if you look at it.

12 And that was a key point that I was making is that I
13 don't see the exponential threat here in the beginning
14 years. Then I saw the introduction of the prescription
15 opioids. My rates were completely flat, and I kept
16 emphasizing that. And then we saw the exponential growth,
17 yes. But it was at the beginning when they were almost
18 entirely new.

19 That's what sets the thing off. And it's not a matter
20 of gateway. I understand I'm not allowed to testify on
21 gateway drugs. But I'm looking at the data. And it was
22 entirely a prescription problem at the beginning. And then
23 there may have been one or two little episodes where there
24 was a few illegal drugs came in.

25 **Q.** Yes, sir. I'm trying to be cognizant of time. So,

1 sir, now I'm going to go to Page 4 of 6.

2 And on Page 4 of 6 it also does the same type of thing.
3 You'll see this.

4 Can you find here which of these charts tracks
5 prescription opioids over time?

6 **A.** Yes. It's the second one.

7 **Q.** So can we highlight the second one?

8 And over time between '99 and 2016, can you walk us
9 through what the time line shows?

10 **A.** The timeline is 1999 to 2003 for the first one. There
11 we go, good. And then it's 2004, 2007, 2008 and 2016. And
12 what I see as, as the dark spot is this is prescription
13 opioids. The dark spots really begin about in 2004, start
14 to see a significant problem, maybe a little bit of a hot
15 spot.

16 I've seen these type of graphs before and they really
17 do start in West Virginia at about 2000. And that's been
18 the remarkable thing to me.

19 **Q.** Yes, sir. Now, let's go back to the ultimate
20 conclusion of why I brought all this up. Let's go to Page 3
21 of 6. So it's the previous page. It's the third column
22 starting here with the word "although," right there.

23 So do you see the sentence here that starts "although"?

24 Can you highlight that sentence, please?

25 It says -- and I'm just going to read one sentence.

1 "Although the overall national epidemic may be smooth and
2 continuous, each drug has shown a specific geo-spatial
3 pattern of spread during this 18-year period."

4 Sir, is this consistent with your testimony?

5 **A.** This is, this is very consistent to the -- and we've
6 been making a big point in our research that the rural drug
7 problem is so different to these national trend studies.

8 **Q.** Now, you can take that down, please.

9 Last thing. I'm going to talk about the death
10 examiner's report that we mentioned earlier for this young
11 man. The first thing I want to point out is the toxicology
12 report.

13 Sir, do you see on the toxicology report what's listed
14 in addition to morphine?

15 **A.** Codeine.

16 **Q.** And what else? You have to look -- flip to Page 542 in
17 the bottom right-hand corner. It's up on your screen.

18 **A.** Oh, good. Yep. They found morphine, codeine. And in
19 the urine they found some evidence of acetaminophen,
20 hydrocodone, dihydrocodeine.

21 **Q.** Last point. I'm not going to pretend that I knew what
22 this word meant. I had to look it up. In the opinion, "The
23 presence of a congener narcotic suggests the possibility
24 that the original injected narcotic was heroin."

25 Regardless of why the medical examiner believed that to

1 be the case, "congener," it's a Latin word. Do you know
2 what it means, sir?

3 **A.** Yeah. It's an associated compound.

4 **Q.** So "con" meaning with, "general" or "genus" meaning a
5 family?

6 It's saying the presence of a narcotic of the same
7 family suggests the possibility that heroin was used.

8 Sir, do you have any independent knowledge as to
9 whether or not codeine, oxycodone, are they in the same
10 family with heroin?

11 **A.** They're all very much in the same family and they
12 actually get metabolized, if I remember correctly, into
13 morphine as well.

14 **Q.** That's because --

15 **A.** They all end up -- morphine is the main drug that they
16 lead to.

17 **Q.** Because it's the same molecule, is it not?

18 **A.** Same molecule, yes.

19 **Q.** Thank you.

20 MR. FARRELL: No further questions. I believe Ann
21 is going to clean up some documents.

22 MS. KEARSE: Just a couple, Your Honor.

23 REDIRECT EXAMINATION

24 BY MS. KEARSE:

25 **Q.** Briefly, when you were -- Doctor, when you were

1 talking about the briefing guide for the first
2 responders on fentanyl, in your research that you did,
3 was it one percent of all overdoses?

4 **A.** This was less than one percent of all overdoses in the
5 U.S. for that period of time. So, in other words, clearly
6 the fentanyl wasn't driving any of the major overdose.
7 There was a little trickle of drugs that were making some
8 impact.

9 And I think it was important, and it was in that
10 article, that there are geographic differences. So there
11 clearly was some. And I didn't see any evidence that those
12 drugs made a huge impact in Cabell County.

13 **Q.** You were shown again the article from 2008, "Patterns
14 of Abuse Among Unintentional Pharmaceutical Overdose
15 Fatalities." I'd like to draw your attention to the comment
16 and then I'm going to show you one other section.

17 Can you read that for the Court?

18 **A.** "In recent years West Virginia has one of the highest
19 unintentional overdose mortality rates in the United States.
20 This study of such deaths in 2006 revealed that almost all
21 of the unintentional drug overdose deaths in West Virginia
22 involved prescription drugs."

23 MS. KEARSE: Gina, if we can turn to Page 2 of
24 that article -- I'm sorry -- Page 2619.

25 BY MS. KEARSE:

1 **Q.** You were asked by Ms. Wu about some information
2 about reports about friends and relatives. Do you
3 recall that?

4 **A.** Yes.

5 **Q.** Okay. Can you read for the Court this paragraph on
6 this paper?

7 **A.** "The Drug Enforcement Administration confirms that drug
8 diversion was widespread in West Virginia and the
9 Appalachian region during this period. The primary methods
10 of diversion were illegal sale and distribution by
11 healthcare professionals, employee theft, forged
12 prescription, and the internet."

13 **Q.** Thank you, Doctor. And, again, this is a study
14 specific to West Virginia; correct?

15 **A.** Yes.

16 **Q.** And, Doctor, you were asked some questions about
17 looking into overdose deaths beyond 2018. And from my
18 understanding of your testimony, you have looked at
19 preliminary data for overdose deaths for -- from 2019 and
20 2020?

21 **A.** Yes, I have.

22 **Q.** And what have you seen in regard to the number of
23 opioid related deaths since this time?

24 **A.** The number of opioid related deaths has also increased
25 dramatically, and we're all really scared. But the data are

1 only preliminary. But even already from the preliminary
2 data, it looks like the numbers are the highest yet we've
3 had for West Virginia.

4 **Q.** And does that include Cabell County?

5 **A.** The data is not specific for Cabell County. Actually,
6 it is for Cabell County and -- but I'd have to go back and
7 look at that.

8 **Q.** Thank you, Doctor.

9 MS. KEARSE: No further questions.

10 THE COURT: Any recross?

11 MS. WU: Very briefly.

12 RE CROSS EXAMINATION

13 BY MS. WU:

14 **Q.** Doctor, Ms. Kearse just asked you about post-2018
15 overdose data for Cabell County; correct?

16 **A.** Yes.

17 **Q.** And you described what I believe was an increase for
18 certain sub periods of time between 2018 and 2020 in
19 overdose deaths; correct?

20 **A.** Correct.

21 **Q.** In referencing an increase in overdose deaths, you're
22 specifically referencing overdoses involving illicit
23 fentanyl; correct?

24 **A.** That would be included -- they would be included in
25 that number.

1 **Q.** And you're also referencing overdose deaths including
2 illicit heroin; correct?

3 **A.** Yes, they would be included.

4 **Q.** Do you know what proportion of prescription -- excuse
5 me. Let me try that again. Do you know how many
6 prescription overdose deaths there were last year?

7 **A.** I cannot remember the -- I just happen to be honest
8 with you that the data is so preliminary and so unreliable
9 that I was not able to obtain a copy through official
10 channels. But the Mountain State Spotlight did a report on
11 it and they had the data.

12 So I'm not -- as an epidemiologist, they're too
13 preliminary for me to look at. But I had the same source
14 that everybody else has to look at.

15 **Q.** So you don't have data sufficiently reliable such that
16 you can offer an opinion as to the rate of overdoses for the
17 period 2018 to 2020; correct?

18 **A.** I can offer an opinion because the preliminary data are
19 the lowest number. And those data -- I'm talking about the
20 final number and we like to be accurate. But to date, that
21 is the, that is what they are. And the numbers always
22 increase over time as they get better classification and
23 decide on the difficult cases.

24 **Q.** Based on that preliminary data, you know that it's
25 illicit fentanyl and heroin that are driving the overdoses

1 in Cabell County; correct?

2 **A.** They are certainly what is driving the overdoses --
3 seem to be what's driving, and the proportion of them that
4 are -- the important thing is, though, it's polypharmacy.
5 And I -- to be honest, I do not know what proportion would
6 also have a prescription opioid involved.

7 **Q.** Thank you, Doctor.

8 THE COURT: Anything else of Dr. Smith?

9 MS. KEARSE: Your Honor, I just have a couple
10 cleanup things with some documents that I failed to offer
11 into evidence earlier.

12 We did present Dr. Smith's report that we're not
13 putting into evidence as P-4227, but I do have several of
14 the, the graphs that we presented to your court that I'd
15 like to move into evidence, Your Honor.

16 THE COURT: Is there any objection to this?

17 MS. WU: I need to see what they are, but I
18 believe those are properly demonstratives and not separate
19 evidence.

20 THE COURT: Aren't those demonstratives,
21 Ms. Kearse? They illustrate his testimony rather than
22 exhibits that ought to be admitted?

23 MS. KEARSE: Your Honor, I believe we've presented
24 the testimony. We've showed them as demonstratives to the
25 report. But they were all part of his report as he

1 testified. They include Exhibit A, which was the, the data
2 that was collected; Exhibit B which was the pre-1999 -- I
3 can show them to Your Honor if that helps.

4 MS. WU: Your Honor, Dr. Smith's report is not
5 independently admissible evidence and there's no shortcut by
6 making them demonstratives. Thank you.

7 THE COURT: I'll sustain the objection,
8 Ms. Kearse. The Court's seen them. You've used them as
9 demonstratives. They're part of his report. His report's
10 not admissible in and of itself.

11 MS. KEARSE: Okay. It's independent of his report
12 because it was data that was actually testified to and laid
13 the foundation for the graphs and the charts that were shown
14 to the Court. So I would ask Your Honor to put them into
15 evidence now and beyond demonstratives. It's separate from
16 his report. He laid the foundation of how this was put
17 together, his own independent research of putting this data
18 together. And it was extensively testified throughout the
19 trial.

20 THE COURT: Ms. Wu?

21 MS. WU: Your Honor, we agree that Mr. Smith's
22 testimony regarding his opinions and analysis are in the
23 record and are admissible. However, these demonstratives
24 used to assist his testimony have no independent evidentiary
25 value and should not be admitted.

1 THE COURT: Yeah. I'm going to sustain the
2 objection. I've seen them and he's testified to them.
3 So --

4 MS. KEARSE: Thank you, Your Honor.

5 THE COURT: I don't think you're damaged too much
6 here.

7 MS. KEARSE: Thank you, Your Honor.

8 THE COURT: Anything else of Dr. Smith?

9 MR. RUBY: Nothing from us, Your Honor.

10 THE COURT: Dr. Smith, thank you, sir, very much.

11 THE WITNESS: Thank you.

12 THE COURT: You've been very helpful to the Court
13 and I can now excuse you and with the Court's thanks. I
14 appreciate it.

15 We have 20 minutes. You're here to cause trouble,
16 aren't you, Mr. Ackerman.

17 MR. ACKERMAN: I'm always here to cause trouble
18 unfortunately.

19 Your Honor, I do recognize the time. We'll need a few
20 minutes to, to switch up. We do have another witness, Dr.
21 Mohr, who's ready to go with appreciation to defendants who
22 have allowed us to call her today instead of tomorrow.

23 I leave it to the Court's discretion whether, you
24 know -- we can get 10 minutes of testimony in, but it's
25 certainly up to the Court.

1 THE COURT: Well, isn't she the one that had an
2 obligation and couldn't be here or something? Is she
3 available tomorrow?

4 MR. ACKERMAN: She -- yes, she is available
5 tomorrow. She, she was available today and tomorrow. She
6 just couldn't come next week.

7 THE COURT: Okay. Let's go ahead and -- we've got
8 20 minutes. Let's go ahead and start and at least we can do
9 that.

10 MR. ACKERMAN: Okay. Your Honor, plaintiffs call
11 Dr. Jakki Mohr.

12 THE COURT: Dr. Mohr, come up here and the clerk
13 will give you the oath.

14 THE CLERK: Would you please state your name.

15 THE WITNESS: Jakki Mohr.

16 THE CLERK: Thank you. Please raise your right
17 hand.

18 **JAKKI MOHR, PLAINTIFFS' WITNESS, SWORN**

19 THE CLERK: Thank you. Please take a seat.

20 DIRECT EXAMINATION

21 BY MR. ACKERMAN:

22 **Q.** Good afternoon, Dr. Mohr.

23 **A.** Hello.

24 **Q.** Would you please introduce yourself to the Court?

25 **A.** Yes. I'm Jakki Mohr. I'm a Professor of Marketing.

1 Q. And, Dr. Mohr, where are you employed?

2 A. I'm at the University of Montana.

3 Q. And what is your title at the University of Montana?

4 A. I'm the Regents Director of Marketing.

5 Q. You can move the microphone a little bit closer to you
6 if at all possible.

7 Dr. Mohr, did you prepare a slide with your credentials
8 to assist in your testimony today?

9 A. Yes, I did.

10 Q. Okay. Would it be useful to put that slide up on the
11 screen?

12 A. Sure.

13 MR. ACKERMAN: Your Honor, I'd ask to publish what
14 appears to be marked as Demo234.

15 BY MR. ACKERMAN:

16 Q. Dr. Mohr, is this the slide that you prepared?

17 A. Yes, it is.

18 Q. Now, you said your role is a Regents Professor; is that
19 correct?

20 A. Uh-huh.

21 Q. What is a Regents Professor?

22 A. It's considered to be a rare designation for a
23 Professor who has achieved international acclaim for her
24 research. She also excels in teaching and service to the
25 state, the community, the university, and her professional

1 discipline.

2 **Q.** And when did you become a Regents Professor?

3 **A.** 2008.

4 **Q.** What classes do you teach at the University of Montana?

5 **A.** I teach a junior-level class called Principles of
6 Marketing to all business students. I teach a senior-level
7 elective called Marketing High Technology Products and
8 Innovations. I teach a specialty course in Data Analytics
9 and Innovation. And in years past, I've taught a
10 Distribution Channels course as well.

11 **Q.** Dr. Mohr, do you have a Ph.D?

12 **A.** Yes, I do.

13 **Q.** And when did you receive your Ph.D?

14 **A.** 1989.

15 **Q.** From where?

16 **A.** University of Wisconsin-Madison.

17 **Q.** And do you have a particular focus or specialty?

18 **A.** Yes, I did. My specialty and my Ph.D. was on
19 distribution channel strategy.

20 **Q.** And did you prepare a dissertation in connection with
21 your Ph.D?

22 **A.** Yes, I did.

23 **Q.** And what was that dissertation?

24 **A.** My dissertation was on the role of communication
25 strategies in coordinating manufacturer efforts with retail

1 distributors.

2 **Q.** Do you have a, a specialty that you focus on at this
3 point?

4 **A.** Yes. My recent focus is on the way companies use
5 technology and innovation in their marketing strategies,
6 particularly technology-driven companies.

7 **Q.** Do you have experience with distribution channels?

8 **A.** Yes, I do.

9 **Q.** And what are distribution channels?

10 **A.** Distribution channels are considered to be the strategy
11 by which manufacturers provide access to their products at
12 the point of purchase.

13 **Q.** Do you have experience analyzing distribution channels
14 in other industries?

15 **A.** Yes. My dissertation research was actually in the
16 computer industry. It was funded by IBM. I've also worked
17 in Silicon Valley in the interface of distribution and
18 advertising working at HP.

19 **Q.** And at what point in time did you work at HP?

20 **A.** It was prior to getting my Ph.D. It was an eon ago.

21 **Q.** For how long did you work at HP?

22 **A.** Only two years.

23 **Q.** And what did you do there?

24 **A.** During my time in Silicon Valley I worked in what was
25 called local advertising, which means I coordinated the

1 retail advertising of HP products with our national brand
2 campaign.

3 So I was responsible in large part for the retail
4 distribution channel in terms of their efforts to push our
5 product in their markets in which they sold.

6 **Q.** Okay. Dr. Mohr, have you published articles on
7 marketing?

8 **A.** Yes, of course.

9 **Q.** About how many?

10 **A.** I'd say 25, 30.

11 **Q.** And what are some representative titles of some
12 articles that you have published?

13 **A.** Some of the articles that I'm most well-known for are
14 my dissertation research in 1990. My dissertation
15 theoretical model was published in the Journal of Marketing.
16 It's an award-winning article that was considered to be one
17 of the seminal articles looking at how distribution channels
18 are coordinated through non-contractual mechanisms,
19 including communication.

20 The title of that article is "Communication Strategies
21 as a Source of Distribution Channel Coordination."
22 Governance is what we call it technically.

23 I have an empirical article that studied the role of
24 communication as a government strategy that was published in
25 1996, also an award-winning article.

1 I have an article in the Strategic Management Journal
2 about how manufacturers and retailers partner in a strategic
3 alliance effort in order to tightly integrate their
4 strategies in what we call a win-win partnership. That was
5 in 1996.

6 And since that time, many of my articles have focused
7 on the role of technology in coordinating distribution
8 channels, especially with the advent of the internet in the
9 year 2000.

10 **Q.** Dr. Mohr, is this another slide that you prepared for
11 us today?

12 **A.** Yes, it is.

13 **Q.** And does this slide list some of the awards that you
14 have won?

15 **A.** Yes. One that I haven't mentioned yet is -- Louis
16 Stern is a very famous marketing professor at Northwestern
17 University. And he has an endowed award in his name through
18 the American Marketing Association. It's called the Stern
19 Award.

20 So in addition to having received that award, I have
21 served on the selection committee for that award over the
22 years.

23 In addition, we in the American Marketing Association
24 give a Lifetime Achievement Award for people who work at the
25 interface of what's called Interorganizational Relationships

1 which is the supply chain essentially. And I do serve on
2 the award committee, or I have served on the award committee
3 for that in years past as well.

4 **Q.** And, in fact, were you the Chair of the Stern Award
5 Selection Committee --

6 **A.** Yes, one year I was.

7 **Q.** -- during your time?

8 **A.** Yes.

9 **Q.** Dr. Mohr, do you serve on any editorial boards for
10 marketing related periodicals?

11 **A.** Yes, of course, I do. I serve on the Editorial Review
12 Boards of several journals. Many of them are what I call
13 subspecialty journals that deal with distribution channel
14 management, as well as business. We call it business to
15 business marketing, so manufacturers to distributors, for
16 example. And then most of my reviewing is in the area of
17 either distribution or increasingly in innovation as well.

18 **Q.** So for about how long, Dr. Mohr, have you studied
19 marketing?

20 **A.** Well, technically, it started as a passion when I was
21 in college. And I have an undergraduate degree in
22 marketing. I have a Master's Degree in marketing. I have a
23 Ph.D. in marketing. And I have worked in marketing prior to
24 my academic career. So dating myself, I've been doing this
25 since about 1978.

1 Q. Where did you receive your undergraduate degree from?

2 A. I'm from Idaho, so I got it at Boise State University.

3 Q. And was there -- you said it was an undergraduate
4 degree in marketing?

5 A. Yes, correct.

6 Q. Is that correct?

7 A. Yes.

8 Q. And when did you receive your Master's Degree?

9 A. I received my Master's Degree at Colorado State
10 University. Part of my love of the west is that when I grew
11 up in Boise, HP had a very large footprint there with the
12 laser printer division.

13 And, so, I did some of my work during my college years
14 with them. And they had a plant in Fort Collins and I was
15 given several job offers with HP after I graduated with my
16 Master's but opted to go to Silicon Valley.

17 MR. ACKERMAN: Your Honor, I would offer Dr. Mohr
18 as an expert in marketing.

19 THE COURT: Any objection?

20 MS. MCCLURE: No objection, Your Honor.

21 MR. HESTER: No objection.

22 MS. WICHT: No objection.

23 THE COURT: The Court finds that Dr. Mohr is, in
24 fact, an expert in the field of marketing.

25 THE WITNESS: Thank you.

1 BY MR. ACKERMAN:

2 Q. Well, we have eight more minutes to go, so let's
3 get started.

4 A. Okay.

5 Q. Dr. Mohr, are you familiar with distribution channels
6 in the pharmaceutical industry?

7 A. Yes, I am.

8 Q. And how did you become familiar with distribution
9 channels in the pharmaceutical industry?

10 A. Typically when we talk about distribution channels,
11 there is an accepted set of strategies and frameworks that
12 would be used and applied across multiple types of
13 industries.

14 So in this particular case, simply being aware of the
15 way the pharmaceutical industry works -- my dad was actually
16 a physician. We had detail people who I knew by name in
17 some cases.

18 But, more generally, just studying distribution allows
19 me to be familiar with pharmaceuticals as well as other
20 industries.

21 Q. And in connection with your work in this case, did you
22 perform any research in order to familiarize yourself or
23 learn more about the distribution channels in the
24 pharmaceutical industry?

25 A. Yes. I definitely am an academic nerd and I love to

1 read. And, so, I did buy several books on pharmaceutical
2 marketing and supply chains in the pharmaceutical industry.

3 I also did read articles by experts in this space.
4 Deloitte had done a consulting project on behalf of the
5 healthcare distribution alliance. And they have a lovely
6 report about the role of distributors in the healthcare in
7 this country.

8 I also did read articles in the Journal of the American
9 Medical Association on financing and distribution and
10 distribution channels, Kaiser Family Foundation. I have to
11 say that I do love reading about distribution channels. My
12 poor partner wonders what's wrong with me.

13 **Q.** Did you, Dr. Mohr, prepare an expert report for use in
14 this case?

15 **A.** Yes, I did.

16 **Q.** And were you asked to prepare opinions for use in this
17 litigation?

18 **A.** Yes, I was.

19 **Q.** And, Dr. Mohr, do you have an opinion as to whether the
20 distributor defendants in this case, or companies affiliated
21 with them, were engaged in marketing of prescription opioid
22 medications?

23 **A.** Yes.

24 **Q.** We'll get to that opinion -- I'm sorry. And what is
25 that opinion?

1 **A.** The opinion is that the distributors did engage in
2 marketing.

3 **Q.** Dr. Mohr, we'll get to that opinion in a little bit.
4 Let's talk about how you worked your way into that opinion.

5 **A.** Uh-huh.

6 **Q.** Did you observe any parallels between distribution
7 channels in the pharmaceutical industry and distribution
8 channels in the high-tech or other industries?

9 **A.** Yes. Again, there's a common set of tools, strategies
10 and frameworks that we use.

11 For example, one of the most common frameworks is we
12 look at what are the efficiencies that distribution channels
13 provide. Often times there's a myth that people believe
14 that if you could only cut out the middleman, you could cut
15 out the margins that these intermediaries or distributors or
16 retailers take as part of the pricing of the product along
17 the channel.

18 The reason that I say that's a myth is because the role
19 of the intermediary is to provide all sorts of efficiencies
20 in different industries. And this is true in the
21 pharmaceutical industry.

22 **Q.** And did you prepare a chart that demonstrates those
23 efficiencies that you're describing?

24 **A.** I did pull a chart out of my report which is a classic
25 chart that's used in all marketing textbooks that classify

1 the way the distribution channel offers efficiencies.

2 **Q.** And is this on the screen the chart that you were
3 describing?

4 **A.** Yes, it is. It's very classic.

5 **Q.** Would you please describe to us what this chart shows?

6 **A.** Yeah. So on the left-hand side we have what's called
7 an unintermediated market, meaning there's no distributor,
8 there's no retailer, there's no channel member.

9 And in a market where there's not an intermediary, for
10 any company listed as a manufacturer on the left to engage
11 in a transaction with a customer, which is on that
12 right-hand side, each manufacturer would have to somehow
13 have a connection with each customer.

14 In marketing we look at this more from the customer
15 perspective. So if I wanted to buy a product, and let's say
16 I wanted to buy a pair of running shoes, if I wanted to
17 evaluate Nike or Adidas or Skecher and we didn't have a
18 retailer where I live, somehow I would have to be able to
19 find each manufacturer's product through their own outlets
20 which, of course, is impossible where I live. It's
21 impossible in lots of places.

22 So the reason that we have on the right-hand side a
23 picture that shows the role of any channel intermediary --
24 in this picture that I pulled, it says distributor. It
25 could also be a retailer. Simply by having a retailer

1 instead of each company having to contact each customer,
2 each company now only has to contact one distributor and
3 each customer only has to go to that one distributor in
4 order to access their goods.

5 So this is a way of providing contact efficiencies in
6 market. And it's a really important hallmark of what we use
7 to kind of ground the role of the distributor in a
8 distribution channel.

9 **Q.** Dr. Mohr, do you have an opinion as to whether the
10 distributor defendants here served as channel intermediaries
11 with respect to the pharmaceutical industry?

12 **A.** Absolutely, yes.

13 **Q.** And what is that opinion?

14 **A.** The distributors in the pharmaceutical industry did
15 play a role as a channel intermediary between the
16 pharmaceutical companies and downstream customers.

17 **Q.** I want to ask you what seems like a very basic question
18 and I suspect it's going to end up with a long answer. But
19 what is marketing?

20 **A.** Yeah. My standard response to that is if you ask 20
21 different people what marketing is, you'll get 20 different
22 answers. So I'm glad you're asking me because I can
23 actually tell you what it is.

24 The purpose of marketing is the thing that I always
25 start with. And the role of marketing clearly is to create

1 awareness of a company's products because as people and
2 customers, we can't engage in purchasing if we don't know it
3 exists.

4 So the language that is typically used for marketing in
5 terms of this awareness function is called to educate and
6 inform. And depending on the industry, we may add persuade
7 to that as well. So creating awareness is educate, inform,
8 and persuade.

9 The second rule of marketing is to influence consumer
10 attitudes and perceptions. And in this particular case, a
11 big part of marketing is to influence people's attitudes
12 about a particular brand or product class as a whole.

13 And then the third most important role of marketing is
14 to execute a transaction, which in -- for purposes here is
15 really to buy a particular product. Marketing is clearly
16 used for non-commercial transactions, for instance, by
17 non-profits and other sorts of organizations. But for
18 commercial purposes, the goal of marketing is to create a
19 sale.

20 **Q.** Now, I've already asked you about your opinion as to
21 whether distributors conducted marketing.

22 **A.** Uh-huh.

23 **Q.** I want to ask a couple questions about that opinion
24 before we get into the bases for it.

25 First of all, did -- in forming your opinion, did you

1 do any analysis specific to West Virginia?

2 **A.** No, I did not.

3 **Q.** And why not?

4 **A.** When I was called to work on this particular case, I
5 was asked to evaluate -- I'm sorry if I'm moving too far
6 away. I was asked to evaluate whether or not distributors
7 engaged in marketing. And, so, it wasn't state specific.
8 It was on a national basis.

9 **Q.** And what did you do in order to form your opinion that
10 distributors defendants or companies affiliated with them
11 engaged in marketing?

12 **A.** I reviewed quite a few pages of evidence and
13 documentation.

14 **Q.** When you say evidence and documentation, what do you
15 mean by that?

16 **A.** I mean that the distributors had -- in boxes that were
17 sent to me, I had marketing materials that the distributors
18 had used to market marketing services. I had evidence from
19 the pharmaceutical manufacturers about the services that
20 distributors performed that would fall under the umbrella of
21 marketing. And in reviewing these documents is how I formed
22 my opinions.

23 **Q.** Okay. And were these documents internal documents from
24 the company?

25 **A.** Yes, in some cases, they were.

1 **Q.** And did they include some external communications?

2 **A.** External communications sometimes could be things in
3 marketing. Again, we might look at magazines. Magazines is
4 the one that comes to mind for me, but also journal articles
5 and things like this nature.

6 THE COURT: When you get to a stopping place,
7 we'll have to adjourn, Mr. Ackerman.

8 MR. ACKERMAN: Let me ask two more questions, Your
9 Honor, and I think we're at a very good stopping place.

10 THE COURT: Okay. Yesterday we were going to get
11 one more question and we got 25. So --

12 MR. ACKERMAN: I've got two on this list, Your
13 Honor.

14 BY MR. ACKERMAN:

15 **Q.** Dr. Mohr, if an expert in your field was assessing
16 a company's marketing, would that expert reasonably rely
17 on the company's internal documents?

18 **A.** Yes, absolutely. Most strategies are written in a
19 company's documents. They engage in a strategic planning
20 process. And based on that strategic planning process, all
21 companies prepare internal brochures. We sometimes call it
22 collateral material that summarizes the essence of that
23 strategy.

24 **Q.** The last question: If an expert in your field was
25 assessing a company's marketing, would that expert

1 reasonably rely on external communications from the company
2 related to marketing?

3 **A.** Yes. I think that's a really important component of
4 this because we want to make sure that we're validating what
5 we're seeing internally. So we want to see evidence of how
6 those strategies were actually deployed in the marketplace.

7 MR. ACKERMAN: And with that, Your Honor, we'll
8 pick it up tomorrow.

9 THE COURT: Dr. Mohr, we're going to have to
10 excuse you until tomorrow morning at 9:00 and we'll see you
11 then.

12 THE WITNESS: Okay. Thank you very much.

13 THE COURT: I'll see everybody else at 9:00 as
14 well.

15 MR. SCHMIDT: Your Honor, may we just give the
16 Court a heads up? I'm sorry.

17 THE COURT: You can step down, Dr. Mohr. You
18 don't have to sit here during this.

19 MR. SCHMIDT: The Court might have seen this
20 already. We put in a supplemental paper on the pending
21 Rafalski motion. It's got two bases. One is just drawing
22 on some of Mr. Rannazzisi's testimony, and the second one is
23 drawing on plaintiffs' decision to not recall Dr. McCann.
24 We just wanted to flag that for the Court.

25 THE COURT: All right. I was informed earlier

1 that you filed that and I'll look at it.

2 MR. FARRELL: Judge, on behalf of the plaintiffs,
3 we just want to flag that we don't think we need to recall
4 Dr. McCann.

5 MR. SCHMIDT: Well, as the paper makes clear, the
6 representation was repeatedly made that Dr. McCann would be
7 recalled. He was offered. Doctor -- Mr. Rafalski was
8 offered under the theory of conditional relevance with the
9 representation that he would be recalled. We weren't able
10 to question him on his methodologies. That's the point we
11 made in the paper.

12 THE COURT: Well, I'll look at the paper and
13 figure it out.

14 MR. FARRELL: We can recall Dr. McCann, I mean, if
15 that's what they'd like. I can put him up for you. I mean,
16 it's the chicken and the egg situation for us.

17 THE COURT: Well, let me read the motion before we
18 go any further, Mr. Farrell.

19 MR. FARRELL: Thank you, sir.

20 THE COURT: Anything else before we adjourn until
21 tomorrow morning?

22 I understand that my decision to go until 5:00
23 tomorrow messed up several people's travel plans and I
24 didn't intend to do that and I apologize for that, but I
25 suppose it's too late to change it. See you in the morning.

1 I distinctly remember telling you if you had any
2 problem with that with regard to your weekend travel to let
3 me know.

4 MR. SCHMIDT: You did.

5 THE COURT: All right. See you in the morning.

6 (Trial recessed at 5:05 p.m.)
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1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,
4 certify that the foregoing is a correct transcript from
5 the record of proceedings in the matter of The City of
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen
7 Drug Corporation, et al., Defendants, Civil Action No.
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as
9 reported on June 10, 2021.

10
11 S\Ayme A. Cochran

12 Reporter

13 s\Lisa A. Cook

14 Reporter

15 —

16 June 10, 202117 Date
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	134 [1] - 204:6 139 [3] - 63:24, 64:5, 85:24 14 [3] - 133:11, 141:18, 194:22 149 [1] - 203:22 15 [1] - 87:20 15910 [1] - 3:18 16 [1] - 133:2 16.6 [2] - 139:24, 140:13 16.7 [1] - 146:21 1600 [1] - 3:17 161 [1] - 207:8 16th [2] - 9:9, 91:8 17 [1] - 140:15 171 [1] - 199:22 1717 [2] - 6:6, 6:13 17th [1] - 87:23 18 [3] - 146:8, 146:15, 152:4 18-year [3] - 199:19, 201:24, 218:3 184 [1] - 204:6 186 [1] - 146:9 19 [2] - 107:21, 185:19 19087 [1] - 6:15 19103 [2] - 6:6, 6:13 1950 [1] - 107:24 19525 [1] - 51:22 1976 [1] - 107:21 1978 [1] - 233:25 1979 [17] - 100:25, 117:2, 117:24, 125:1, 125:23, 128:1, 128:17, 128:24, 129:7, 131:18, 156:10, 191:6, 193:1, 194:8, 195:1, 197:10, 198:11 198 [1] - 146:7 1980 [3] - 104:5, 107:21, 197:24 1989 [1] - 229:14 199 [1] - 128:24 1990 [1] - 231:14 1990s [1] - 197:11 1993 [2] - 52:18, 54:4 1996 [2] - 231:25, 232:5 1998 [4] - 7:21, 194:4, 195:7, 198:11 1999 [3] - 131:18, 147:13, 217:10 1999-2000 [1] - 195:1 19th [1] - 71:1 1st [1] - 47:20	2 2 [24] - 24:21, 24:24, 29:4, 33:17, 46:24, 47:4, 70:9, 86:7, 86:22, 139:25, 141:17, 147:7, 150:11, 158:9, 158:19, 159:10, 159:19, 172:17, 178:9, 178:11, 193:14, 193:16, 196:9, 220:23 2.3 [1] - 188:6 2.3.2 [1] - 187:15 20 [5] - 142:25, 226:15, 227:8, 239:20, 239:21 200 [1] - 112:7 2000 [13] - 128:18, 128:24, 130:8, 130:12, 131:22, 180:15, 181:2, 194:8, 194:10, 197:24, 198:2, 217:17, 232:9 20001 [1] - 5:12 20004 [1] - 4:7 20005 [3] - 4:14, 4:16, 5:5 2001 [34] - 117:21, 124:2, 127:15, 131:9, 132:1, 132:14, 132:17, 132:22, 132:25, 134:1, 135:5, 135:16, 136:7, 136:11, 138:3, 138:8, 138:12, 139:5, 139:25, 145:15, 156:10, 157:3, 157:16, 158:1, 158:2, 158:8, 177:18, 188:6, 199:19, 200:14, 201:25, 206:3, 215:17, 215:25 2003 [2] - 143:22, 217:10 2004 [4] - 147:13, 147:24, 217:11, 217:13 2005 [16] - 7:18, 7:21, 8:17, 9:9, 9:13, 20:8, 21:7, 49:13, 50:1, 62:18, 161:24, 179:15, 180:16, 180:18, 180:21, 181:2 2006 [16] - 47:6, 62:24,	63:22, 64:11, 64:20, 65:11, 74:9, 92:11, 143:1, 143:15, 146:5, 165:7, 183:4, 183:16, 183:23, 220:20 2007 [24] - 22:5, 22:8, 22:9, 23:25, 24:5, 24:6, 26:23, 32:20, 33:6, 33:12, 47:6, 47:7, 68:10, 69:5, 70:2, 70:5, 71:1, 73:5, 171:20, 173:6, 179:15, 180:22, 217:11 2008 [15] - 47:3, 142:13, 142:24, 142:25, 144:4, 146:5, 149:18, 149:21, 182:17, 182:20, 183:24, 217:11, 220:13, 229:3 2009 [1] - 47:21 2010 [3] - 49:15, 211:11, 212:10 2011 [10] - 74:10, 135:5, 136:4, 138:3, 138:8, 158:13, 164:14, 177:10, 177:19, 178:5 2012 [5] - 41:1, 199:23, 200:16, 200:24, 211:14 2013 [9] - 38:21, 39:16, 58:25, 59:13, 138:24, 141:1, 141:5, 178:7, 202:12 2014 [8] - 178:13, 178:20, 179:12, 182:2, 202:3, 202:13, 202:16, 213:18 2015 [3] - 27:8, 188:7, 202:13 2016 [16] - 142:22, 148:20, 149:23, 150:4, 186:2, 187:8, 188:14, 189:19, 190:5, 191:6, 193:1, 201:10, 202:17, 202:21, 217:8, 217:11 2017 [15] - 45:1, 86:21, 87:23, 88:4, 88:10, 140:14, 161:24, 202:17, 202:21, 203:16, 203:19, 203:25, 204:5, 204:6, 204:13	2018 [39] - 117:24, 124:2, 125:1, 125:23, 127:17, 128:2, 129:7, 132:14, 132:17, 132:22, 134:2, 135:17, 138:12, 139:5, 141:21, 145:16, 158:8, 199:19, 199:23, 200:14, 200:17, 200:20, 201:10, 201:25, 202:3, 202:18, 202:22, 203:16, 203:22, 203:25, 204:5, 204:6, 204:13, 204:19, 206:3, 206:22, 221:17, 222:18, 223:17 2019 [1] - 221:19 202 [3] - 2:4, 2:16, 203:20 2020 [6] - 91:8, 131:22, 165:7, 221:20, 222:18, 223:17 2021 [4] - 1:19, 7:4, 246:9, 246:15 21 [4] - 47:16, 48:1, 93:4 21.4 [1] - 146:10 213.9 [1] - 140:14 214 [1] - 140:15 219 [1] - 206:23 2216 [1] - 3:7 233 [1] - 102:25 234 [1] - 147:2 24 [2] - 1:16, 146:16 25 [3] - 5:5, 231:10, 242:11 251 [1] - 199:18 25301 [3] - 2:8, 3:13, 4:19 25322 [1] - 6:9 25338-3843 [1] - 5:15 25701 [1] - 3:10 2619 [1] - 220:24 27 [2] - 172:5, 173:2 27-year-old [3] - 170:2, 170:9, 170:14 271 [1] - 146:8 275 [1] - 147:4 279 [1] - 146:23 27th [2] - 47:6, 47:7 28 [3] - 3:15, 4:3, 4:9 29 [1] - 172:14 29464 [3] - 3:15, 4:4, 4:9 295 [2] - 144:25, 146:7
'01 [1] - 206:22 '12 [2] - 38:21, 74:10 '99 [1] - 217:8	0 0 [1] - 40:14 00131 [1] - 171:10 00131-A [1] - 171:11 00907 [2] - 2:5, 2:17 02191 [1] - 32:25	1 1 [9] - 25:5, 172:7, 175:18, 180:12, 182:25, 189:10, 192:22, 193:4 1% [1] - 181:8 1(b) [1] - 25:14 1,000 [1] - 206:9 1,002 [3] - 134:5, 134:8, 206:9 1,013 [1] - 180:22 1,151 [4] - 134:8, 135:17, 201:23, 206:6 10 [9] - 1:19, 7:4, 46:13, 187:18, 187:20, 187:23, 226:24, 246:9, 246:15 100 [1] - 190:15 100,000 [5] - 194:3, 194:6, 195:2, 195:9, 198:11 1001 [2] - 2:10, 4:6 1022 [1] - 3:5 10th [2] - 9:13, 50:1 11 [2] - 91:10, 135:7 11th [1] - 33:6 12 [4] - 37:22, 79:15, 137:15, 141:18 122 [1] - 147:5 126 [1] - 3:5 127 [2] - 37:22, 200:16 128 [1] - 91:8 129 [1] - 200:12 12th [2] - 33:6, 49:13 13 [6] - 50:20, 138:1, 187:13, 187:15, 187:17, 187:18 1300 [1] - 6:15 1301 [1] - 72:15 1301.74 [1] - 56:16 1301.74(b) [1] - 48:1 1302.74(b) [1] - 47:16 1311 [2] - 2:4, 2:16		

2:00 [3] - 119:5, 119:8, 119:14	56 [1] - 3:4 56th [1] - 3:5 59 [3] - 42:2, 94:16, 200:20 5:00 [1] - 244:22 5:05 [1] - 245:6 5th [1] - 171:20	9	235:25 acceleration [1] - 197:12 accent's [1] - 103:10 accept [1] - 82:3 acceptance [1] - 87:2 accepted [3] - 104:9, 120:22, 235:11 access [7] - 88:9, 126:22, 162:16, 163:1, 163:11, 230:11, 239:4 accessed [1] - 164:5 accident [2] - 172:18, 172:25 accidental [9] - 126:6, 127:22, 127:24, 130:4, 130:15, 131:24, 156:11, 156:20, 172:21 acclaim [1] - 228:23 accompanied [1] - 146:11 accordance [1] - 93:24 According [3] - 194:2, 201:23, 207:22 according [5] - 48:20, 177:3, 204:9, 207:7, 208:5 Accountability [1] - 60:18 accounted [3] - 202:11, 202:16, 202:20 accounts [2] - 34:11, 34:25 accuracy [1] - 101:23 accurate [6] - 27:20, 28:8, 39:12, 79:4, 80:3, 223:20 accurately [2] - 40:5, 65:3 acetaminophen [1] - 218:19 achieved [1] - 228:23 Achievement [1] - 232:24 ACKERMAN [19] - 2:9, 31:20, 31:22, 32:6, 66:19, 66:23, 96:14, 226:17, 227:4, 227:10, 227:21, 228:13, 228:15, 234:17, 235:1, 242:8, 242:12, 242:14, 243:7 Ackerman [3] - 83:10, 226:16, 242:7 acknowledge [1] -	47:19 acknowledged [2] - 48:17, 65:12 act [1] - 93:12 Act [1] - 92:22 Acting [5] - 41:18, 42:13, 43:18, 43:21, 44:10 acting [1] - 94:12 Action [4] - 1:4, 1:10, 246:7, 246:8 action [7] - 16:3, 18:20, 36:25, 37:4, 37:8, 37:11, 41:13 actions [1] - 14:20 activities [1] - 10:9 activity [4] - 11:10, 12:6, 14:19, 15:9 acts [2] - 84:22, 92:22 actual [5] - 60:17, 133:24, 134:19, 211:3 acute [1] - 66:8 add [5] - 78:10, 80:16, 103:12, 104:23, 240:6 added [2] - 19:21, 189:15 addicted [1] - 108:4 addiction [3] - 162:19, 162:23, 213:2 addicts [1] - 85:2 addition [6] - 26:2, 27:18, 76:12, 218:14, 232:20, 232:23 additional [6] - 19:22, 20:7, 43:2, 108:8, 149:19, 179:4 address [4] - 17:5, 44:14, 59:22, 168:5 addressed [3] - 52:12, 52:13, 53:4 adept [1] - 50:16 adequately [1] - 163:21 Adidas [1] - 238:17 adjourn [2] - 242:7, 244:20 adjunct [1] - 101:8 adjust [1] - 129:23 adjusted [4] - 129:7, 129:17, 129:24, 194:24 Administration [2] - 180:4, 221:7 Administration's [1] - 61:18 Administrations' [1] - 61:14		
3	6	9 [4] - 42:3, 140:17, 140:22, 199:8 9-D [1] - 171:24 901 [1] - 4:18 90s [3] - 55:3, 56:13, 62:16 91 [4] - 152:10, 152:19, 186:7, 186:16 91.9 [1] - 146:8 91436 [1] - 3:18 93 [1] - 151:18 93.2 [1] - 147:5 94.6 [1] - 146:24 95 [2] - 134:10, 135:10 98 [1] - 40:15 99% [2] - 40:9, 40:16 9:00 [3] - 7:4, 243:10, 243:13 9:52 [1] - 36:13 9th [1] - 2:10				
3 [9] - 29:3, 46:25, 87:1, 122:7, 134:2, 171:18, 195:14, 195:17, 217:20 30 [12] - 26:15, 28:22, 101:18, 143:25, 151:22, 151:24, 173:15, 190:6, 190:9, 190:12, 208:23, 231:10 30-day [1] - 152:1 3100 [2] - 6:5, 6:12 316 [1] - 2:13 32502 [1] - 2:14 33 [1] - 146:21 35 [2] - 101:18, 146:20 36 [2] - 88:3, 152:12 36% [1] - 151:23 38 [2] - 197:15, 210:4 3843 [1] - 5:14 3:17-cv-01362 [2] - 1:5, 246:8 3:17-cv-01665 [2] - 1:11, 246:8 3rd [1] - 65:11	6 [9] - 184:3, 195:14, 195:17, 196:25, 197:1, 197:2, 217:1, 217:2, 217:21 6-MAM [3] - 165:24, 166:1, 166:8 6-Monoacetylmorphine [1] - 165:22 60 [4] - 89:18, 89:22, 95:7, 207:23 600 [1] - 2:13 63 [2] - 146:10 657 [1] - 202:2 66,000 [1] - 13:4 67.1 [1] - 146:7 6th [1] - 3:5	A				
4	7	a.m [2] - 7:4, 36:13 ABDC [2] - 162:21, 203:1 ability [1] - 25:9 able [14] - 115:3, 118:5, 118:6, 125:1, 126:8, 132:10, 133:5, 150:21, 156:16, 170:6, 205:4, 223:9, 238:18, 244:9 absolutely [18] - 10:11, 53:17, 53:20, 65:8, 82:20, 90:16, 113:22, 114:1, 120:2, 120:7, 120:17, 126:20, 138:10, 150:15, 151:11, 153:7, 154:20, 242:18 Absolutely [3] - 31:21, 35:19, 239:12 Abuse [3] - 110:20, 144:2, 220:14 abuse [7] - 106:24, 106:25, 111:14, 112:3, 112:9, 144:19, 146:23 abusing [1] - 184:6 academia [2] - 101:17, 121:13 academic [6] - 101:3, 106:20, 112:6, 166:6, 233:24,	7 [8] - 47:6, 79:16, 129:2, 129:5, 184:2, 184:4, 184:25, 185:22 70 [1] - 89:18 70130 [1] - 3:8 707 [1] - 4:18 70s [1] - 52:9 716 [1] - 3:12 725 [2] - 4:13, 4:15 75 [2] - 157:25, 158:1 76 [1] - 128:25 79.3 [1] - 147:3			
5	8	8 [1] - 131:12 801 [1] - 3:10 801(c)(2) [1] - 57:22 803(8) [2] - 59:19, 60:14 80s [1] - 52:9 830 [2] - 152:10, 188:13 842(a)(5) [1] - 48:2 850 [1] - 5:12 86 [1] - 188:15 87 [2] - 135:12, 135:14 8th [1] - 52:18				
5 [13] - 30:8, 46:12, 83:22, 92:16, 126:11, 139:21, 175:25, 176:14, 176:15, 192:2, 197:1, 197:2 50 [2] - 89:18, 89:22 54 [1] - 146:8 542 [1] - 218:16 550% [1] - 147:14 553 [1] - 6:8						

administrative [3] - 38:24, 40:2, 61:14 Administrator [11] - 9:7, 41:18, 42:13, 43:11, 43:19, 43:21, 44:1, 47:8, 56:11, 58:23, 62:25 Administrator's [1] - 44:10 admissible [6] - 59:19, 169:14, 174:24, 225:5, 225:10, 225:23 admission [3] - 25:1, 45:5, 174:11 admit [8] - 59:12, 60:21, 60:24, 167:24, 170:25, 171:6, 174:8, 175:11 admitted [10] - 8:21, 20:2, 31:25, 32:1, 32:24, 169:18, 171:1, 174:7, 224:22, 225:25 adopts [1] - 95:10 advance [1] - 62:24 Advancement [1] - 191:14 advent [1] - 232:8 advertising [3] - 230:18, 230:25, 231:1 advised [3] - 21:19, 39:8, 62:22 Advisory [2] - 101:13, 108:21 affected [1] - 129:21 affiliate [1] - 101:9 affiliated [3] - 107:5, 236:20, 241:10 affirmed [1] - 44:11 afraid [1] - 7:8 afternoon [5] - 119:18, 182:22, 209:12, 209:13, 227:22 afterwards [1] - 32:4 age [6] - 129:7, 129:17, 129:24, 146:16, 146:22, 194:24 age-adjusted [2] - 129:7, 129:17 age-specific [1] - 129:24 aged [2] - 146:8, 146:20 agencies [2] - 180:16, 180:19 agency [3] - 43:12,	94:23, 95:10 agency's [1] - 74:4 agent [1] - 52:15 ago [11] - 52:16, 55:3, 62:15, 85:22, 95:9, 101:15, 156:21, 191:17, 198:9, 199:11, 230:20 agree [15] - 17:9, 17:19, 19:14, 43:22, 61:19, 61:21, 68:24, 74:1, 78:3, 79:5, 165:24, 184:21, 214:17, 225:21 agreed [4] - 14:15, 25:16, 25:22, 29:7 Agreement [12] - 24:8, 24:11, 24:17, 25:2, 26:22, 29:11, 32:17, 32:22, 45:2, 47:1, 47:2, 86:22 agreement [17] - 17:5, 24:22, 25:15, 26:4, 26:13, 27:22, 27:23, 28:21, 28:24, 29:16, 45:9, 46:10, 46:11, 46:14, 47:22, 72:3, 87:22 agrees [2] - 75:7, 78:17 ahead [17] - 14:3, 38:15, 45:8, 46:7, 50:13, 51:5, 58:4, 65:23, 67:16, 68:3, 69:14, 70:22, 76:3, 80:24, 83:19, 227:7, 227:8 al [4] - 1:7, 1:13, 246:6, 246:7 alarming [1] - 180:20 alcohol [2] - 109:24, 110:13 ALJ [2] - 42:4, 42:6 allegedly [1] - 12:11 alley [1] - 122:18 alliance [2] - 232:3, 236:5 allow [6] - 38:14, 60:10, 80:22, 80:24, 116:17, 212:5 allowed [4] - 22:15, 38:23, 216:20, 226:22 allows [2] - 125:11, 235:18 almost [10] - 36:5, 54:21, 99:7, 140:15, 160:10, 160:22, 194:13, 216:17, 220:20	aloud [2] - 40:19, 175:20 Alprazolam [5] - 21:6, 206:20, 206:25, 207:3, 207:15 altered [1] - 17:22 AM-WV-00649 [1] - 24:18 AM-WV-01079 [1] - 20:2 AM-WV-649 [1] - 31:24 America [1] - 216:1 American [9] - 93:23, 103:24, 108:11, 108:13, 144:3, 191:13, 232:18, 232:23, 236:8 Amerisource [2] - 28:4, 31:5 AmerisourceBergen [55] - 6:2, 7:18, 8:12, 8:18, 9:15, 11:16, 11:20, 12:5, 13:11, 14:17, 14:18, 14:19, 16:14, 17:3, 17:14, 17:19, 18:10, 18:19, 19:13, 19:15, 19:21, 20:6, 20:9, 20:20, 20:25, 21:4, 21:9, 21:15, 21:24, 22:19, 23:20, 24:2, 24:7, 24:10, 24:13, 24:16, 25:2, 25:15, 25:18, 26:6, 26:20, 26:23, 29:15, 29:17, 29:21, 30:10, 30:15, 30:20, 34:1, 50:3, 50:5, 63:2, 209:5, 246:6 AMERISOURCEBERGEN [2] - 1:7, 1:13 AmerisourceBergen's [10] - 8:6, 13:23, 22:8, 22:12, 24:1, 29:8, 29:10, 29:14, 30:12, 63:5 Amitriptyline [3] - 208:21, 208:24, 209:2 amorphous [1] - 55:8 amount [1] - 212:17 analgesics [1] - 147:4 analyses [2] - 125:20, 172:11 analysis [6] - 111:16, 149:22, 165:10, 166:17, 225:22, 241:1 Analysis [2] - 150:5, 186:2	Analytics [1] - 229:8 analyze [2] - 42:5, 42:6 analyzing [1] - 230:13 ancient [1] - 54:21 AND [1] - 44:9 ANDREW [1] - 5:10 anecdotal [1] - 174:25 anesthetize [1] - 203:8 Ann [1] - 219:20 ANNE [1] - 4:2 ANNIE [1] - 3:14 announce [3] - 43:12, 94:23, 95:10 announced [1] - 95:16 annual [1] - 195:21 annually [2] - 30:11, 30:20 answer [22] - 13:16, 13:17, 37:14, 38:14, 38:17, 38:20, 39:14, 44:3, 45:7, 63:12, 66:9, 71:19, 75:25, 82:19, 83:1, 90:23, 91:16, 91:17, 102:3, 161:9, 213:12, 239:18 answered [1] - 38:11 answers [4] - 41:6, 61:13, 91:15, 239:22 Anthony [1] - 57:17 ANTHONY [1] - 2:6 anti [1] - 44:19 anti-diversion [1] - 44:19 apologize [7] - 17:24, 19:17, 65:20, 69:12, 119:7, 198:15, 244:24 Appalachian [3] - 111:18, 111:22, 221:9 appear [3] - 19:12, 53:12, 114:3 APPEARANCES [6] - 2:1, 3:1, 5:1, 5:6, 6:1, 6:10 applicable [2] - 126:19, 128:11 applicant [1] - 39:17 applicants [3] - 38:3, 38:5, 39:1 application [2] - 99:25, 106:7 applications [2] - 38:24, 40:2 applied [3] - 92:2, 120:19, 235:12 applies [1] - 99:22	apply [1] - 98:15 applying [2] - 91:21, 111:5 appointment [2] - 106:20, 109:1 appointments [1] - 101:3 appreciate [1] - 226:14 appreciation [1] - 226:21 approach [23] - 8:22, 19:4, 24:19, 45:13, 48:23, 51:23, 58:6, 67:19, 68:25, 70:7, 74:15, 102:6, 138:16, 139:14, 143:3, 149:3, 167:11, 169:15, 171:2, 174:1, 179:21, 191:2, 209:21 appropriate [8] - 14:20, 16:8, 27:20, 68:16, 74:4, 82:15, 94:6, 171:9 appropriately [1] - 94:10 approval [1] - 62:21 approved [3] - 62:20, 62:23, 178:1 April [2] - 22:8, 22:18 Arch [2] - 6:6, 6:13 archaical [1] - 118:5 ARCOS [9] - 25:8, 25:9, 25:25, 26:2, 27:18, 28:9 area [13] - 59:9, 98:15, 99:8, 99:11, 99:25, 100:1, 100:4, 100:6, 100:14, 107:23, 111:2, 115:13, 233:16 areas [11] - 98:23, 99:5, 99:25, 107:11, 107:23, 111:7, 112:4, 112:8, 180:21, 216:4 argue [2] - 57:13, 57:14 argues [3] - 42:24, 43:12, 94:22 argument [5] - 43:14, 57:14, 60:10, 78:1, 94:25 article [56] - 74:25, 75:8, 78:6, 127:7, 142:25, 143:6, 143:8, 143:9, 143:10, 144:2,
---	---	---	---	--

<p>182:17, 182:20, 183:14, 183:24, 184:3, 184:19, 184:21, 184:22, 185:18, 186:10, 190:25, 191:4, 191:10, 191:22, 192:3, 192:7, 193:3, 193:5, 193:8, 195:12, 195:13, 195:14, 196:17, 196:22, 196:24, 197:1, 204:9, 209:17, 209:18, 209:25, 211:4, 211:17, 212:3, 212:24, 213:5, 213:21, 214:6, 214:16, 220:10, 220:13, 220:24, 231:16, 231:20, 231:23, 231:25, 232:1</p> <p>articles [13] - 112:6, 112:7, 121:7, 184:20, 192:13, 231:6, 231:12, 231:13, 231:17, 232:6, 236:3, 236:8, 242:4</p> <p>ASHLEY [1] - 5:3</p> <p>aside [2] - 177:8, 185:25</p> <p>aspect [2] - 35:20, 106:2</p> <p>aspects [4] - 76:15, 168:14, 169:11, 187:12</p> <p>assessing [2] - 242:15, 242:25</p> <p>assigned [2] - 8:15, 114:21</p> <p>assignment [6] - 114:21, 114:23, 114:25, 115:1, 115:24, 115:25</p> <p>assist [4] - 100:12, 143:11, 225:24, 228:8</p> <p>Assistant [7] - 9:6, 47:7, 56:11, 58:23, 74:9, 106:19, 106:20</p> <p>assistant [1] - 101:4</p> <p>associated [10] - 12:5, 136:25, 146:9, 163:18, 164:4, 199:18, 200:9, 200:13, 201:7, 219:3</p> <p>Association [6] - 108:13, 144:4,</p>	<p>191:13, 232:18, 232:23, 236:9</p> <p>assume [4] - 12:16, 27:23, 202:8, 202:19</p> <p>Assuming [1] - 188:19</p> <p>AT [1] - 1:2</p> <p>attached [4] - 18:3, 18:8, 18:15, 18:16</p> <p>attempt [2] - 45:24, 163:17</p> <p>attempting [2] - 56:20, 57:3</p> <p>attend [3] - 9:24, 10:1, 79:23</p> <p>attended [1] - 9:14</p> <p>attention [17] - 12:14, 13:15, 33:16, 74:21, 150:9, 171:18, 171:23, 176:7, 179:13, 180:14, 184:2, 188:2, 192:2, 193:20, 195:13, 197:3, 220:15</p> <p>attitudes [2] - 240:10, 240:11</p> <p>attorney [1] - 55:18</p> <p>Attorney [2] - 37:1, 37:11</p> <p>attorney-client [1] - 55:18</p> <p>attorney/client [1] - 15:12</p> <p>attribute [2] - 163:5, 163:8</p> <p>attributed [1] - 180:23</p> <p>attributes [1] - 173:4</p> <p>audit [2] - 68:10, 69:4</p> <p>audits [2] - 69:20, 70:1</p> <p>August [5] - 9:9, 9:13, 29:21, 49:13, 50:1</p> <p>auspices [1] - 35:7</p> <p>authenticated [1] - 59:20</p> <p>author [1] - 145:11</p> <p>authored [1] - 192:8</p> <p>authority [5] - 55:12, 77:2, 77:3, 77:4, 77:13</p> <p>authors [5] - 192:3, 193:13, 193:24, 196:6, 197:8</p> <p>autopsies [1] - 174:15</p> <p>autopsy [1] - 123:3</p> <p>Autopsy [1] - 176:23</p> <p>availability [1] - 182:1</p> <p>available [15] - 59:21, 116:2, 124:25, 132:16, 149:16, 150:7, 175:3, 175:6,</p>	<p>177:21, 177:24, 178:1, 184:10, 227:3, 227:4, 227:5</p> <p>average [2] - 188:5, 194:2</p> <p>Avin [2] - 3:7, 57:18</p> <p>avoid [2] - 83:9, 83:13</p> <p>award [7] - 231:16, 231:25, 232:17, 232:20, 232:21, 233:2</p> <p>Award [3] - 232:19, 232:24, 233:4</p> <p>award-winning [2] - 231:16, 231:25</p> <p>awards [1] - 232:13</p> <p>aware [30] - 17:13, 20:8, 21:4, 21:15, 23:19, 28:25, 44:10, 44:18, 44:23, 45:1, 45:9, 46:9, 52:25, 66:12, 68:9, 69:4, 74:3, 75:5, 165:6, 165:8, 166:5, 166:14, 181:1, 181:4, 181:5, 183:13, 213:13, 213:20, 235:14</p> <p>awareness [3] - 240:1, 240:5, 240:7</p> <p>Awareness [1] - 58:14</p> <p>axis [1] - 215:11</p> <p>Ayme [2] - 6:17, 246:2</p>	<p>basis [15] - 8:4, 9:21, 22:2, 48:9, 55:23, 56:5, 60:25, 89:4, 113:16, 120:15, 153:4, 165:3, 174:25, 188:10, 241:8</p> <p>bat [1] - 129:12</p> <p>Baylen [1] - 2:13</p> <p>become [3] - 23:19, 229:2, 235:8</p> <p>becoming [2] - 56:11, 106:14</p> <p>BEFORE [1] - 1:17</p> <p>beforehand [2] - 192:15, 198:3</p> <p>began [4] - 54:14, 180:20, 198:20, 211:14</p> <p>begin [2] - 9:2, 217:13</p> <p>beginning [11] - 10:4, 117:11, 124:5, 126:2, 136:3, 180:18, 184:7, 184:9, 216:13, 216:17, 216:22</p> <p>begins [4] - 26:10, 49:20, 81:6, 94:18</p> <p>begun [1] - 133:1</p> <p>behalf [5] - 35:11, 57:7, 57:18, 236:4, 244:2</p> <p>belabor [2] - 19:8, 33:5</p> <p>belief [1] - 77:11</p> <p>believes [2] - 161:4, 189:12</p> <p>below [2] - 94:5, 194:3</p> <p>BENCH [1] - 1:16</p> <p>benefits [1] - 162:14</p> <p>benzodiazepines [1] - 64:24</p> <p>Bergen [3] - 62:14, 62:19, 62:22</p> <p>best [9] - 17:5, 98:9, 98:20, 115:1, 115:2, 123:9, 127:12, 162:13, 162:16</p> <p>better [6] - 17:11, 107:14, 109:4, 109:13, 148:1, 223:22</p> <p>between [33] - 7:21, 8:18, 17:2, 17:3, 20:9, 56:2, 65:11, 71:3, 72:2, 98:10, 122:21, 126:14, 135:16, 139:5, 156:3, 178:24, 180:15, 180:21,</p>	<p>199:19, 200:13, 200:16, 201:10, 202:3, 203:16, 203:25, 207:19, 211:18, 211:25, 216:3, 217:8, 222:18, 237:6, 239:15</p> <p>beyond [6] - 179:4, 211:23, 213:7, 213:8, 221:17, 225:15</p> <p>big [6] - 111:13, 113:3, 113:8, 141:5, 218:6, 240:11</p> <p>binding [2] - 42:7, 42:9</p> <p>bit [22] - 67:2, 83:25, 103:6, 107:12, 109:1, 109:7, 114:20, 120:3, 121:18, 124:17, 137:1, 142:5, 148:20, 158:7, 162:4, 164:9, 181:6, 183:19, 190:11, 217:14, 228:5, 237:3</p> <p>black [1] - 215:5</p> <p>blank [1] - 169:8</p> <p>block [2] - 87:14, 214:24</p> <p>blocked [4] - 12:9, 13:4, 14:15, 87:18</p> <p>blood [2] - 110:13, 123:2</p> <p>Bloomberg [1] - 101:11</p> <p>blow [2] - 211:1, 211:10</p> <p>blue [1] - 136:4</p> <p>Blvd [3] - 3:15, 4:3, 4:9</p> <p>Board [2] - 101:13, 108:21</p> <p>boards [1] - 233:9</p> <p>Boards [1] - 233:12</p> <p>body [3] - 123:3, 155:25, 166:11</p> <p>Boggs [14] - 74:8, 74:9, 75:1, 75:2, 75:18, 75:24, 76:8, 76:12, 76:14, 76:21, 78:5, 78:16, 78:23, 79:4</p> <p>boggs [1] - 75:6</p> <p>Boggs' [3] - 76:15, 77:18, 78:12</p> <p>Boise [2] - 234:2, 234:11</p> <p>Bonasso [1] - 5:14</p>
B				
<p>b) [2] - 25:5, 30:9</p> <p>baby [1] - 175:10</p> <p>background [12] - 38:3, 38:4, 38:22, 39:7, 39:16, 39:22, 64:10, 81:14, 91:19, 103:6, 103:7, 103:8</p> <p>balances [1] - 41:11</p> <p>Barber [1] - 66:13</p> <p>Baron [1] - 3:17</p> <p>base [4] - 21:9, 21:10, 73:12, 73:13</p> <p>based [15] - 17:9, 47:25, 55:16, 61:21, 61:23, 68:20, 88:21, 88:22, 111:23, 123:7, 157:22, 190:21, 202:16, 242:20</p> <p>Based [3] - 11:18, 12:20, 223:24</p> <p>bases [2] - 240:24, 243:21</p> <p>basic [1] - 239:17</p>				

books [2] - 112:10, 236:1 born [1] - 103:11 borrow [1] - 158:11 borrowing [1] - 178:9 bottom [17] - 51:8, 87:4, 87:5, 92:16, 92:17, 130:11, 136:5, 180:14, 187:19, 187:23, 207:22, 208:14, 208:23, 210:8, 211:7, 218:17 Boulevard [1] - 3:18 box [3] - 144:7, 144:23, 207:22 Box [8] - 5:14, 6:8, 171:18, 171:24, 172:5, 172:14, 173:2, 173:15 boxes [2] - 83:14, 241:16 brand [3] - 81:21, 231:1, 240:12 brazenness [1] - 11:10 break [8] - 15:3, 36:11, 38:2, 118:24, 119:24, 128:21, 182:4, 182:9 Brick [1] - 10:14 brick [5] - 10:21, 10:23, 10:25, 12:16, 12:22 Bridgeside [3] - 3:15, 4:3, 4:9 brief [4] - 36:17, 36:18, 80:25, 155:14 briefed [10] - 17:16, 17:17, 20:17, 50:10, 52:22, 53:7, 54:14, 56:10, 62:25, 63:1 briefing [9] - 10:7, 13:6, 49:24, 50:5, 50:8, 51:14, 55:9, 179:25, 220:1 briefings [7] - 20:6, 20:24, 63:4, 69:22, 69:23, 69:25, 71:4 Briefly [1] - 219:25 briefly [5] - 106:15, 109:16, 116:23, 133:13, 222:11 bring [4] - 77:24, 90:6, 137:4, 210:25 bringing [3] - 12:14, 62:8, 109:9 broad [6] - 98:8, 100:8, 118:13, 128:20, 130:6, 205:2	broader [1] - 106:1 brochures [1] - 242:21 broke [2] - 147:17, 211:5 brought [9] - 13:14, 36:25, 37:11, 63:16, 103:11, 108:15, 109:12, 179:13, 217:20 Brunswig [2] - 62:14, 62:22 Brunswig's [1] - 62:19 Budd [1] - 3:17 building [2] - 30:24, 113:14 built [2] - 27:22, 27:23 bulk [3] - 112:8, 127:24, 147:17 bullet [6] - 10:2, 10:3, 11:5, 11:9, 24:25, 79:20 burdensome [1] - 43:2 Burling [1] - 5:11 business [16] - 12:7, 21:25, 22:19, 23:20, 25:19, 28:17, 73:11, 73:13, 73:19, 81:6, 82:7, 82:13, 229:6, 233:14, 233:15 buy [4] - 236:1, 238:15, 238:16, 240:15 buying [1] - 154:5 BY [106] - 7:11, 7:16, 8:25, 13:19, 14:4, 15:18, 18:2, 19:7, 20:4, 24:23, 32:8, 33:19, 34:21, 36:20, 37:7, 37:25, 38:19, 46:23, 48:16, 48:24, 51:7, 51:24, 53:21, 54:9, 54:25, 56:9, 58:8, 61:5, 63:17, 65:25, 67:17, 68:6, 69:2, 69:17, 70:8, 70:23, 71:24, 74:7, 74:17, 75:17, 76:7, 78:22, 81:2, 83:4, 83:21, 84:2, 85:14, 85:20, 91:18, 94:21, 97:20, 99:20, 102:22, 105:8, 105:21, 112:25, 115:22, 119:19, 121:2, 122:8, 126:12, 128:7, 129:4, 131:13, 135:9, 135:24, 136:20, 137:17,	138:2, 139:16, 140:18, 141:19, 143:5, 144:8, 144:24, 147:9, 149:5, 151:3, 152:5, 153:13, 154:11, 155:7, 161:19, 167:13, 171:13, 175:14, 179:23, 182:15, 191:3, 194:20, 199:9, 205:20, 209:11, 209:23, 211:2, 212:6, 213:16, 214:22, 215:22, 219:24, 220:25, 222:13, 227:21, 228:15, 235:1, 242:14 <div style="text-align: center;">C</div> CA [1] - 3:18 Cabell [69] - 3:2, 23:2, 23:7, 57:18, 87:12, 100:24, 111:3, 113:25, 114:1, 114:2, 114:9, 114:14, 114:25, 115:4, 116:1, 117:9, 128:21, 130:22, 132:23, 132:25, 133:8, 133:10, 134:3, 135:18, 136:7, 138:8, 139:22, 139:23, 141:12, 145:4, 156:15, 158:15, 163:4, 163:7, 163:16, 163:25, 164:3, 165:6, 166:18, 171:24, 172:11, 174:14, 177:10, 178:13, 178:20, 181:18, 182:1, 196:12, 196:16, 196:20, 197:20, 198:10, 198:13, 200:13, 201:4, 201:24, 202:12, 202:21, 203:16, 204:13, 204:18, 206:3, 220:12, 222:4, 222:5, 222:6, 222:15, 224:1 CABELL [1] - 1:10 cabell [1] - 2:2 Cabell-Huntington [5] - 113:25, 114:1, 114:2, 114:25,	141:12 cabinet [1] - 88:13 calculated [2] - 135:11 calculator [1] - 202:9 CALLAS [2] - 6:7, 209:6 campaign [1] - 231:2 CAMPBELL [1] - 6:14 cannot [3] - 15:12, 161:3, 223:7 capacity [2] - 90:9, 90:10 Capitol [1] - 2:7 capture [1] - 62:11 captured [1] - 62:10 car [1] - 109:25 card [1] - 36:16 Cardinal [5] - 4:11, 5:2, 162:22, 203:1, 205:22 Cardinal's [1] - 72:12 care [2] - 13:24, 96:11 career [3] - 100:6, 105:20, 233:24 careful [1] - 168:15 Carey [1] - 4:17 carries [2] - 184:4, 204:22 carry [1] - 102:1 carrying [1] - 119:25 carryover [1] - 94:17 case [57] - 8:13, 35:10, 41:19, 43:8, 66:18, 86:4, 103:10, 114:21, 114:25, 116:24, 116:25, 120:1, 120:6, 120:20, 124:14, 126:19, 141:9, 148:6, 150:19, 155:9, 155:18, 156:3, 156:5, 157:1, 157:23, 159:14, 163:24, 164:11, 165:4, 165:14, 167:22, 170:13, 170:24, 172:12, 172:21, 173:4, 173:12, 177:7, 178:4, 178:23, 179:5, 179:9, 180:7, 181:3, 181:15, 190:16, 198:21, 199:1, 203:1, 205:7, 219:1, 235:14, 235:21, 236:14, 236:20, 240:10, 241:4 cases [19] - 99:7,	120:16, 124:6, 134:10, 138:22, 160:16, 174:14, 178:16, 183:19, 206:23, 207:8, 207:23, 208:6, 208:15, 208:24, 223:23, 235:17, 241:25 categories [1] - 215:5 categorization [1] - 170:21 categorized [2] - 177:4, 177:20 category [8] - 118:7, 127:1, 127:4, 128:20, 129:1, 130:6, 130:14, 130:15 caught [1] - 206:18 causal [1] - 189:12 causation [1] - 211:24 caused [12] - 140:25, 159:5, 160:8, 160:12, 160:18, 164:13, 166:21, 166:22, 189:9, 189:20, 190:7, 190:13 causes [7] - 100:2, 100:3, 107:6, 107:22, 123:6, 125:20, 174:20 causing [4] - 130:17, 133:21, 160:14, 164:8 CDC [18] - 89:2, 105:1, 121:11, 121:12, 123:21, 123:23, 124:18, 124:20, 124:21, 124:24, 125:23, 126:22, 128:1, 129:17, 130:2, 147:19, 152:22, 194:8 CDC's [1] - 192:4 ceased [1] - 21:25 Center [7] - 3:12, 5:11, 108:22, 117:16, 118:3, 123:16, 124:12 center [4] - 7:20, 8:7, 24:2, 185:1 Centers [10] - 88:23, 89:8, 104:10, 104:13, 104:22, 117:25, 141:1, 143:10, 148:17, 194:11 centers [4] - 7:20,
--	--	---	---	---

<p>7:21, 29:10, 29:14 Central [3] - 81:19, 81:23, 123:4 centralized [1] - 82:6 centrally [1] - 117:16 certain [18] - 22:19, 47:23, 58:17, 76:15, 81:8, 81:10, 81:14, 82:4, 82:5, 87:7, 87:17, 87:18, 98:13, 169:11, 170:5, 222:18 certainly [7] - 60:19, 67:13, 136:15, 161:1, 213:8, 224:2, 226:25 certainty [1] - 154:13 certificate [27] - 123:7, 123:13, 123:15, 124:8, 124:22, 124:23, 132:7, 145:19, 146:1, 159:4, 159:8, 160:6, 160:8, 167:17, 167:20, 168:12, 168:19, 169:3, 169:8, 169:9, 169:17, 170:10, 173:11, 175:9, 175:22, 177:7, 189:11 certificates [22] - 121:22, 125:8, 133:17, 134:18, 143:15, 145:1, 145:17, 146:5, 149:23, 149:24, 158:24, 164:17, 164:19, 164:21, 165:3, 165:7, 165:8, 165:9, 165:11, 165:13, 174:15, 177:11 CERTIFICATION [1] - 246:1 certify [1] - 246:4 CFR [2] - 47:16, 48:1 Ch.B [1] - 103:20 chain [15] - 34:11, 35:1, 40:24, 79:17, 81:4, 81:17, 81:21, 81:22, 82:6, 82:8, 82:10, 82:23, 189:12, 233:1 chains [1] - 236:2 chair [2] - 108:24, 109:3 Chair [1] - 233:4 challenges [1] - 67:9 challenging [1] -</p>	<p>55:23 change [6] - 36:12, 43:3, 139:18, 161:18, 203:25, 244:25 changed [5] - 15:22, 17:22, 139:5, 196:13, 204:18 changes [2] - 44:24, 214:1 Changing [1] - 191:5 channel [11] - 125:16, 229:19, 231:4, 233:13, 237:17, 238:1, 238:8, 238:23, 239:8, 239:10, 239:15 Channel [1] - 231:21 channels [16] - 223:10, 230:7, 230:9, 230:10, 230:13, 231:17, 232:8, 235:5, 235:9, 235:10, 235:23, 236:10, 236:11, 237:7, 237:8, 237:12 Channels [1] - 229:10 chapters [1] - 112:10 characteristics [2] - 10:8, 144:17 characterization [3] - 37:3, 43:25, 65:16 characterizing [1] - 215:19 charge [3] - 52:15, 90:14, 93:3 Charge [1] - 81:13 CHARLES [1] - 3:11 CHARLESTON [2] - 1:2, 1:18 Charleston [7] - 2:8, 3:13, 4:19, 5:15, 6:9, 7:3, 123:5 chart [18] - 128:2, 133:13, 134:15, 135:3, 140:17, 143:23, 203:19, 205:18, 206:1, 206:12, 206:17, 207:7, 210:10, 237:22, 237:24, 237:25, 238:2, 238:5 Chart [1] - 193:20 charted [2] - 159:9, 159:19 charts [3] - 116:12, 217:4, 225:13 Chase [1] - 4:18 check [4] - 92:1, 186:24, 203:6, 203:9</p>	<p>checked [1] - 146:1 checking [1] - 164:24 checks [9] - 38:3, 38:4, 38:23, 39:7, 39:16, 39:22, 41:11, 41:16, 91:20 chemical [2] - 165:22, 166:1 chemicals [1] - 181:22 Chesterbrook [1] - 6:15 Chicago [1] - 180:20 chicken [1] - 244:16 chief [2] - 9:15, 9:17 Chief [1] - 160:4 cholera [1] - 98:21 chose [1] - 35:21 chronic [1] - 66:8 Circuit [1] - 44:12 circulating [1] - 133:21 circumstances [4] - 64:14, 64:19, 64:22, 86:12 Citalopram [3] - 208:12, 208:16, 208:18 citation [1] - 185:17 citations [2] - 43:10, 95:12 cited [2] - 183:14, 184:22 cites [1] - 95:15 cities [1] - 198:7 CITY [1] - 1:4 City [4] - 4:1, 5:11, 23:2, 246:5 Civil [3] - 1:4, 246:7, 246:8 civil [2] - 1:10, 37:3 clandestine [3] - 138:25, 141:3, 180:17 clarify [2] - 15:19, 146:12 clarity [2] - 151:12, 161:8 class [2] - 229:5, 240:12 classes [1] - 229:4 classic [8] - 99:10, 99:13, 120:24, 121:1, 154:2, 216:8, 237:24, 238:4 classification [3] - 100:12, 100:23, 223:22 Classification-10 [1] - 100:18 classifications [1] -</p>	<p>170:5 classified [1] - 101:1 classify [2] - 101:2, 237:25 clause [1] - 86:12 clean [1] - 219:21 cleanup [1] - 224:10 clear [15] - 28:15, 28:16, 32:3, 53:15, 78:4, 127:14, 130:11, 131:15, 142:8, 144:1, 147:10, 148:9, 161:14, 169:7, 244:5 clearer [1] - 17:4 clearly [8] - 128:18, 130:17, 137:21, 151:21, 220:5, 220:11, 239:25, 240:15 CLERK [6] - 97:7, 97:10, 97:13, 227:14, 227:16, 227:19 clerk [1] - 227:12 client [1] - 55:18 clinic [1] - 212:13 clinical [2] - 98:11, 107:10 clinician [1] - 185:12 clinicians [1] - 146:18 clinics [1] - 62:7 Clonazepam [3] - 207:20, 207:23, 208:1 close [3] - 31:18, 32:21, 67:23 closed [5] - 41:5, 41:9, 41:10, 41:14 closer [2] - 122:14, 228:5 co [2] - 34:1, 192:3 co-authors [1] - 192:3 co-presenters [1] - 34:1 Coast [1] - 110:7 cocaine [8] - 199:19, 199:22, 201:20, 203:4, 203:7, 203:10, 206:15 Cochran [3] - 6:17, 246:2, 246:11 coded [3] - 123:20, 124:11, 173:5 Codeine [1] - 218:15 codeine [3] - 176:19, 218:18, 219:9 codes [4] - 100:17, 100:23, 101:2, 126:23</p>	<p>coding [5] - 100:12, 123:18, 124:24, 157:10, 165:10 cogitate [1] - 68:5 cognizant [2] - 16:5, 216:25 collaborate [2] - 101:5, 110:4 collaborated [1] - 101:12 Collaborative [1] - 108:12 collateral [1] - 242:22 colleague [1] - 77:17 colleagues [1] - 110:4 collect [2] - 118:3, 123:1 collected [5] - 122:17, 127:15, 131:3, 132:5, 225:2 collecting [1] - 122:10 collection [3] - 121:21, 191:23, 192:1 college [2] - 233:21, 234:13 College [1] - 108:11 Collins [1] - 234:14 Colorado [3] - 12:11, 104:24, 234:9 Column [1] - 134:2 column [30] - 42:5, 42:21, 84:1, 94:16, 132:17, 133:11, 135:20, 136:21, 180:15, 185:1, 192:18, 192:23, 195:18, 197:4, 200:8, 201:6, 206:20, 207:5, 207:19, 207:22, 208:3, 208:5, 208:11, 208:14, 208:20, 208:23, 211:8, 212:7, 215:14, 217:21 columns [2] - 133:15, 133:25 combed [2] - 130:20, 130:21 combine [1] - 211:4 combined [2] - 103:16, 103:17 combining [1] - 129:11 coming [7] - 17:20, 25:10, 30:24, 99:8, 106:14, 109:17, 112:13 comment [7] - 43:14, 80:11, 94:24, 95:8,</p>
---	--	--	---	---

<p>95:11, 174:13, 220:15</p> <p>commenter [1] - 85:1</p> <p>commerce [3] - 9:16, 9:17, 14:15</p> <p>commercial [2] - 240:16, 240:18</p> <p>COMMISSION [1] - 1:10</p> <p>Commission [4] - 2:2, 3:2, 111:19, 111:22</p> <p>commit [2] - 84:21, 92:21</p> <p>committee [3] - 232:21, 233:2</p> <p>Committee [1] - 233:5</p> <p>common [6] - 10:7, 146:19, 161:20, 201:3, 237:9, 237:11</p> <p>commonly [5] - 152:18, 166:6, 201:13, 207:15, 207:17</p> <p>communication [3] - 229:24, 231:19, 231:24</p> <p>Communication [1] - 231:20</p> <p>communications [5] - 55:15, 55:16, 242:1, 242:2, 243:1</p> <p>community [20] - 93:12, 98:12, 98:13, 98:18, 106:3, 106:4, 106:5, 106:8, 108:4, 112:16, 113:25, 114:1, 114:3, 114:25, 141:12, 177:16, 177:25, 182:2, 228:25</p> <p>companies [8] - 99:6, 136:24, 230:4, 230:6, 236:20, 239:16, 241:10, 242:21</p> <p>company [6] - 14:20, 238:10, 239:1, 239:2, 241:24, 243:1</p> <p>company's [5] - 240:1, 242:16, 242:17, 242:19, 242:25</p> <p>compare [5] - 19:11, 129:18, 129:21, 198:25</p> <p>compared [4] - 136:9, 146:21, 166:11, 186:21</p> <p>comparisons [1] - 129:15</p>	<p>compiled [4] - 120:9, 120:12, 124:19, 124:21</p> <p>compiling [1] - 165:10</p> <p>complete [2] - 60:1, 138:12</p> <p>completely [1] - 216:15</p> <p>completeness [1] - 37:19</p> <p>Completeness [1] - 60:24</p> <p>compliance [2] - 30:12, 44:19</p> <p>component [4] - 127:9, 152:17, 172:25, 243:3</p> <p>components [1] - 8:1</p> <p>comport [1] - 150:11</p> <p>compound [1] - 219:3</p> <p>compounds [1] - 213:18</p> <p>computer [3] - 6:19, 102:2, 230:16</p> <p>con [1] - 219:4</p> <p>concentrated [1] - 111:6</p> <p>concentration [2] - 9:22</p> <p>concentrations [2] - 110:13, 111:12</p> <p>concern [5] - 12:23, 30:16, 83:10, 137:4</p> <p>concerned [3] - 107:25, 133:1, 144:14</p> <p>concerns [2] - 16:1, 30:14</p> <p>conclude [2] - 130:4, 152:13</p> <p>concluded [1] - 152:15</p> <p>concluding [1] - 94:3</p> <p>conclusion [3] - 153:17, 192:19, 217:20</p> <p>conclusions [4] - 163:16, 164:2, 174:19, 210:1</p> <p>conclusive [1] - 153:19</p> <p>condition [1] - 160:11</p> <p>conditional [1] - 244:8</p> <p>conditions [1] - 98:14</p> <p>conduct [7] - 29:8, 38:3, 38:4, 45:23, 46:1, 46:20, 69:10</p> <p>conducted [6] - 68:9, 69:4, 148:1, 149:10, 176:23, 240:21</p>	<p>conducting [3] - 12:11, 43:23, 69:19</p> <p>conference [9] - 32:19, 32:20, 32:21, 33:5, 33:12, 33:13, 33:14, 33:24, 35:18</p> <p>Conference [1] - 58:15</p> <p>conferences [2] - 32:13, 35:8</p> <p>confident [1] - 127:11</p> <p>confidentiality [1] - 126:25</p> <p>confines [2] - 73:18, 81:15</p> <p>confirm [2] - 33:24, 175:21</p> <p>confirms [2] - 216:2, 221:7</p> <p>conformed [1] - 76:16</p> <p>conforms [1] - 73:11</p> <p>confusing [1] - 142:24</p> <p>confusion [1] - 187:25</p> <p>congener [3] - 176:19, 218:23, 219:1</p> <p>Congress [7] - 41:1, 41:9, 89:20, 89:24, 90:4, 90:7, 90:18</p> <p>congressional [1] - 40:9</p> <p>connection [13] - 24:11, 25:1, 55:19, 56:2, 165:14, 166:17, 172:21, 173:12, 186:6, 187:8, 229:20, 235:21, 238:13</p> <p>Connolly [2] - 4:13, 5:4</p> <p>CONROY [1] - 3:3</p> <p>consequence [1] - 18:20</p> <p>consider [8] - 162:18, 163:8, 163:12, 181:25, 189:25, 190:1, 192:7, 196:15</p> <p>consideration [1] - 181:14</p> <p>considered [10] - 98:18, 106:6, 141:4, 141:6, 141:7, 151:24, 178:14, 228:22, 230:10, 231:16</p> <p>considers [1] - 141:2</p> <p>consistent [11] - 54:13, 56:22, 81:10, 89:9, 125:17, 181:20, 186:15, 194:6, 194:11,</p>	<p>218:4, 218:5</p> <p>constant [1] - 131:5</p> <p>constitutes [1] - 72:13</p> <p>consult [1] - 122:21</p> <p>consultant [1] - 105:1</p> <p>consultation [2] - 14:14, 113:7</p> <p>consulting [1] - 236:4</p> <p>consumer [1] - 240:9</p> <p>consuming [1] - 99:18</p> <p>contact [5] - 80:6, 145:11, 239:1, 239:2, 239:5</p> <p>contain [1] - 154:7</p> <p>contained [6] - 26:11, 47:14, 47:25, 116:9, 157:5, 157:7</p> <p>contains [2] - 131:8, 189:22</p> <p>contaminated [1] - 99:13</p> <p>content [1] - 191:18</p> <p>contention [1] - 95:9</p> <p>context [7] - 80:18, 80:21, 81:4, 85:6, 144:9, 144:10, 144:11</p> <p>continue [6] - 22:19, 153:5, 153:21, 184:25, 197:16, 204:8</p> <p>continued [7] - 27:7, 64:21, 141:14, 142:9, 147:23, 154:15, 204:11</p> <p>Continued [5] - 3:1, 5:1, 5:6, 6:1, 6:10</p> <p>continues [6] - 27:4, 84:19, 92:19, 185:7, 188:13, 193:9</p> <p>continuous [1] - 218:2</p> <p>contractual [1] - 231:18</p> <p>contrast [1] - 11:25</p> <p>contributed [4] - 123:13, 159:2, 160:5, 161:2</p> <p>contributing [7] - 134:14, 159:15, 159:18, 160:15, 162:3, 189:24, 190:1</p> <p>contribution [1] - 161:5</p> <p>contributory [2] - 146:25, 147:2</p> <p>Control [17] - 9:7, 9:13, 29:9, 47:8, 52:9, 53:1, 53:25, 88:24, 89:8, 104:10, 104:13, 104:22,</p>	<p>118:1, 141:2, 143:11, 148:17, 194:12</p> <p>Controlled [2] - 92:22, 151:15</p> <p>controlled [24] - 23:1, 25:20, 26:5, 26:24, 30:13, 30:15, 47:10, 64:13, 64:15, 64:21, 66:17, 69:5, 70:3, 72:20, 83:6, 84:3, 88:17, 93:22, 94:4, 146:17, 151:18, 186:8, 186:12, 186:20</p> <p>controls [1] - 44:7</p> <p>conversation [2] - 61:12, 84:9</p> <p>conversely [1] - 163:12</p> <p>conveyed [2] - 66:16, 82:20</p> <p>convinced [1] - 108:23</p> <p>Cook [3] - 6:18, 246:3, 246:11</p> <p>coordinated [2] - 230:25, 231:18</p> <p>coordinating [2] - 229:25, 232:7</p> <p>Coordination [1] - 231:21</p> <p>copied [1] - 129:14</p> <p>copies [2] - 102:15, 129:10</p> <p>copy [12] - 83:9, 83:15, 102:17, 102:23, 103:1, 124:23, 165:9, 182:18, 182:20, 194:15, 199:25, 223:9</p> <p>corner [6] - 92:17, 171:19, 180:11, 210:9, 211:8, 218:17</p> <p>corporation [4] - 1:7, 1:13, 81:18</p> <p>Corporation [3] - 6:2, 63:21, 246:7</p> <p>Correct [23] - 33:12, 191:15, 198:12, 200:15, 200:18, 201:15, 201:22, 203:14, 203:24, 204:16, 206:5, 206:8, 206:11, 206:24, 207:25, 208:2, 208:8, 208:10, 208:17, 208:19, 209:1,</p>
--	--	--	---	---

<p>210:14, 222:20 correct [280] - 9:7, 9:8, 9:10, 9:11, 9:17, 9:18, 9:19, 9:25, 10:11, 10:13, 11:2, 11:3, 11:17, 11:20, 12:15, 12:24, 13:8, 15:5, 19:22, 22:9, 22:13, 22:23, 22:24, 23:3, 23:7, 23:11, 24:8, 24:9, 24:11, 24:12, 24:14, 25:3, 25:4, 26:2, 26:3, 26:7, 27:1, 27:3, 27:8, 27:23, 27:25, 28:23, 29:6, 29:12, 29:18, 29:22, 29:25, 32:19, 33:6, 33:7, 35:7, 35:18, 35:22, 44:25, 49:15, 49:16, 50:11, 50:12, 52:11, 52:23, 54:8, 60:5, 61:25, 84:12, 85:4, 86:4, 86:24, 87:15, 87:18, 88:11, 88:24, 89:13, 89:14, 89:20, 90:16, 94:12, 95:4, 95:17, 112:16, 113:21, 114:4, 114:5, 131:19, 132:7, 135:15, 135:21, 144:5, 145:17, 145:22, 151:7, 152:23, 155:18, 156:5, 156:12, 156:13, 156:24, 156:25, 157:3, 157:13, 157:17, 157:18, 157:23, 158:3, 158:15, 158:16, 158:24, 159:3, 159:12, 159:13, 159:16, 159:19, 159:22, 159:23, 160:1, 160:2, 160:6, 160:19, 160:24, 161:10, 161:11, 161:21, 161:22, 161:25, 162:1, 162:6, 162:15, 162:19, 162:20, 162:23, 163:1, 163:5, 163:10, 163:14, 163:25, 164:6, 164:14, 164:15, 164:17, 164:21, 165:4, 165:19, 165:22, 165:23, 166:2, 166:6, 166:7,</p>	<p>166:12, 166:13, 166:15, 166:19, 166:23, 167:6, 167:18, 167:22, 167:23, 171:22, 172:12, 172:13, 172:15, 172:16, 172:22, 173:4, 173:9, 173:10, 173:12, 177:1, 177:5, 177:12, 177:16, 177:22, 177:23, 177:25, 178:6, 178:13, 178:20, 178:21, 178:25, 179:1, 179:5, 179:9, 179:12, 180:4, 180:5, 180:7, 181:3, 181:15, 182:2, 182:22, 182:23, 183:9, 183:25, 184:1, 184:19, 184:23, 185:18, 185:19, 185:22, 186:9, 186:13, 186:22, 187:5, 187:9, 188:11, 188:21, 189:1, 189:2, 189:9, 189:21, 189:24, 190:7, 190:14, 190:21, 191:14, 191:20, 192:9, 194:9, 195:9, 196:9, 196:13, 196:17, 196:22, 197:22, 198:22, 199:1, 199:12, 199:13, 199:15, 200:14, 200:17, 200:20, 200:21, 200:24, 201:4, 201:14, 201:21, 201:25, 202:5, 202:6, 202:7, 202:13, 202:14, 202:18, 202:22, 203:2, 203:5, 203:17, 203:20, 203:23, 204:2, 204:3, 204:6, 204:15, 205:7, 205:24, 205:25, 206:7, 207:3, 207:4, 207:9, 207:13, 208:1, 208:7, 208:9, 208:16, 208:18, 209:2, 210:13, 213:5, 215:17, 221:14, 222:15, 222:19, 222:23,</p>	<p>223:2, 223:17, 224:1, 228:19, 234:5, 234:6, 246:4 corrected [1] - 30:7 correction [1] - 162:12 correctly [11] - 10:10, 42:11, 43:16, 47:12, 47:17, 48:3, 91:24, 160:25, 185:24, 190:16, 219:12 correlation [1] - 213:22 correspondence [2] - 54:1, 66:12 corridor [1] - 180:23 counsel [28] - 36:23, 37:10, 40:8, 41:19, 44:18, 55:16, 58:16, 61:7, 61:13, 64:1, 67:3, 67:4, 72:12, 85:7, 85:16, 102:10, 102:15, 155:8, 155:15, 156:19, 165:18, 168:5, 168:9, 168:23, 170:4, 174:5, 182:17, 199:12 counsel's [1] - 158:11 count [1] - 159:15 counted [2] - 166:18, 181:9 counties [3] - 23:9, 110:21, 111:21 country [11] - 59:7, 103:23, 110:24, 179:15, 179:16, 179:20, 181:10, 185:20, 198:7, 216:4, 236:7 counts [1] - 133:19 COUNTY [1] - 1:10 county [9] - 113:23, 113:24, 122:24, 133:2, 133:6, 145:5, 164:1, 171:24, 178:17 County [64] - 2:2, 3:2, 23:2, 57:18, 100:25, 111:3, 111:23, 111:24, 114:9, 114:14, 115:4, 116:1, 116:2, 117:9, 128:21, 130:22, 132:23, 133:8, 133:10, 134:4, 135:18, 136:7, 138:8, 139:22, 139:23, 145:4, 156:15, 158:15, 163:4, 163:7,</p>	<p>163:17, 163:25, 164:3, 165:6, 165:8, 166:18, 172:11, 174:15, 177:10, 178:13, 178:20, 181:18, 182:1, 196:13, 196:16, 196:20, 197:21, 198:10, 198:14, 200:13, 201:4, 201:24, 202:12, 202:21, 203:16, 204:14, 204:19, 206:4, 220:12, 222:4, 222:5, 222:6, 222:15, 224:1 couple [10] - 33:4, 33:8, 112:23, 119:20, 142:6, 209:9, 209:16, 219:22, 224:9, 240:23 course [8] - 102:9, 128:21, 201:16, 229:8, 229:10, 231:8, 233:11, 238:20 Court [62] - 6:17, 6:18, 7:2, 66:24, 67:4, 95:9, 95:12, 97:22, 98:6, 98:17, 103:1, 105:24, 109:1, 114:7, 114:24, 117:4, 122:3, 122:13, 122:16, 124:17, 126:13, 126:18, 128:9, 129:8, 130:3, 132:5, 132:11, 134:2, 135:4, 136:9, 137:1, 138:13, 139:20, 140:21, 142:5, 142:15, 142:17, 143:7, 144:10, 146:3, 148:19, 149:6, 151:4, 151:12, 156:21, 159:10, 168:9, 194:19, 205:4, 205:16, 220:17, 221:5, 225:14, 226:12, 226:25, 227:24, 234:23, 243:16, 243:19, 243:24, 246:2, 246:3 court [7] - 36:4, 36:12, 44:14, 102:17, 119:4, 121:4, 224:14 COURT [172] - 1:1, 1:17, 7:5, 7:10, 7:14,</p>	<p>8:23, 13:24, 14:2, 15:15, 19:5, 24:20, 32:7, 36:2, 36:4, 36:8, 36:11, 36:14, 37:5, 38:15, 38:18, 44:3, 45:7, 45:14, 45:20, 46:7, 46:16, 46:21, 48:9, 48:12, 51:3, 51:17, 53:15, 53:18, 54:8, 54:18, 55:11, 55:24, 56:5, 56:24, 57:13, 57:19, 58:1, 58:7, 59:16, 60:21, 63:12, 65:21, 67:12, 67:15, 67:20, 67:22, 68:1, 68:24, 69:1, 69:11, 69:13, 70:21, 71:15, 71:22, 74:6, 75:3, 75:10, 75:14, 75:22, 77:14, 78:9, 78:15, 78:20, 80:7, 80:15, 80:22, 82:17, 82:22, 83:1, 85:10, 95:20, 96:1, 96:5, 96:9, 96:12, 96:18, 96:21, 96:25, 97:6, 97:15, 98:24, 99:2, 102:12, 102:19, 105:3, 105:15, 114:11, 114:16, 115:18, 115:20, 118:25, 119:3, 119:7, 119:14, 119:16, 120:25, 139:15, 140:1, 140:8, 143:4, 153:9, 153:11, 153:23, 154:23, 154:25, 155:2, 155:5, 161:18, 167:12, 168:1, 168:11, 168:24, 169:16, 169:23, 170:15, 170:25, 171:4, 171:6, 171:10, 174:7, 174:10, 174:17, 175:2, 175:10, 179:22, 182:4, 182:7, 182:13, 205:11, 209:5, 209:7, 209:22, 211:22, 212:1, 212:5, 212:22, 213:9, 214:13, 214:17, 214:20, 215:20, 222:10, 224:8, 224:16, 224:20, 225:7, 225:20, 226:1, 226:5, 226:8,</p>
--	---	--	---	---

<p>226:10, 226:12, 227:1, 227:7, 227:12, 234:19, 234:23, 242:6, 242:10, 243:9, 243:13, 243:17, 243:25, 244:12, 244:17, 244:20, 245:5</p> <p>Court's [7] - 168:8, 168:22, 174:4, 174:9, 225:8, 226:13, 226:23</p> <p>courtroom [1] - 7:6</p> <p>COURTROOM [3] - 97:7, 97:10, 97:13</p> <p>cover [4] - 49:4, 84:15, 125:3, 125:5</p> <p>covered [4] - 45:5, 45:17, 47:22, 163:22</p> <p>Covington [1] - 5:11</p> <p>crack [1] - 155:2</p> <p>crackdown [1] - 84:5</p> <p>crashes [2] - 109:22, 109:25</p> <p>create [3] - 85:2, 239:25, 240:18</p> <p>created [3] - 122:17, 132:9, 180:3</p> <p>creating [1] - 240:7</p> <p>credentials [1] - 228:7</p> <p>credible [1] - 184:19</p> <p>crew [1] - 143:10</p> <p>criminal [7] - 39:7, 39:16, 40:1, 84:21, 84:24, 92:1, 92:21</p> <p>crisis [1] - 197:4</p> <p>criticism [4] - 74:1, 75:20, 75:25, 76:10</p> <p>criticized [1] - 73:22</p> <p>CROSS [3] - 85:13, 155:6, 205:19</p> <p>cross [7] - 7:7, 25:7, 46:5, 85:10, 205:12, 212:25, 213:8</p> <p>cross-examination [1] - 7:7</p> <p>cross-examined [1] - 212:25</p> <p>CRR [2] - 6:17, 6:18</p> <p>crude [1] - 129:22</p> <p>CSA [5] - 84:4, 84:22, 93:2, 93:8, 93:14</p> <p>CSMP [1] - 151:20</p> <p>cull [9] - 37:20, 72:15, 79:13, 83:7, 87:4, 87:24, 88:4, 91:7, 180:14</p> <p>current [6] - 143:24, 151:23, 151:25,</p>	<p>152:11, 154:17, 210:4</p> <p>cursor [1] - 19:19</p> <p>curve [10] - 133:3, 196:6, 196:16, 196:18, 196:21, 197:10, 197:14, 197:21, 197:24, 210:11</p> <p>curves [2] - 195:19, 197:23</p> <p>customer [13] - 12:10, 21:9, 21:10, 34:9, 34:24, 73:12, 73:13, 82:4, 238:11, 238:13, 238:14, 239:1, 239:3</p> <p>customers [16] - 11:16, 11:20, 12:6, 18:11, 20:10, 20:11, 20:22, 21:1, 21:17, 21:18, 21:25, 22:1, 22:3, 22:20, 239:16, 240:2</p> <p>cut [9] - 21:24, 21:25, 22:4, 59:5, 68:2, 175:10, 193:6, 237:14</p> <p>cut-down [1] - 59:5</p> <p>CV [6] - 102:18, 102:23, 103:1, 112:17, 112:19, 114:18</p>	<p>121:10, 121:11, 121:12, 121:15, 121:16, 121:19, 121:20, 122:1, 122:5, 122:10, 122:12, 122:16, 123:8, 123:15, 123:17, 124:1, 124:10, 124:14, 124:18, 124:19, 124:20, 124:21, 124:22, 125:1, 125:6, 125:11, 125:16, 125:23, 126:2, 126:14, 126:15, 126:18, 127:2, 127:14, 128:1, 128:17, 128:23, 129:6, 129:7, 129:9, 129:13, 129:14, 130:2, 130:4, 130:22, 130:23, 130:24, 130:25, 131:3, 131:7, 131:9, 132:3, 132:4, 132:5, 132:9, 132:15, 132:20, 132:23, 133:5, 133:9, 133:10, 135:2, 135:4, 136:2, 136:6, 138:6, 138:20, 142:1, 142:12, 145:3, 145:16, 145:25, 147:19, 149:16, 150:21, 150:23, 151:5, 151:6, 151:7, 152:6, 152:8, 156:17, 156:20, 157:23, 158:21, 159:1, 163:11, 164:16, 164:18, 165:3, 165:10, 165:16, 167:22, 172:23, 173:3, 177:3, 178:23, 179:4, 183:15, 183:18, 186:18, 189:19, 194:7, 194:11, 194:12, 194:14, 195:7, 195:8, 196:20, 197:20, 198:15, 199:14, 200:22, 202:16, 203:14, 204:10, 204:21, 205:3, 205:4, 216:21, 221:19, 221:25, 222:2, 222:5, 222:15, 223:8,</p>	<p>223:11, 223:15, 223:18, 223:19, 223:24, 225:1, 225:12, 225:17</p> <p>Data [1] - 229:8</p> <p>database [15] - 88:8, 88:10, 88:11, 111:8, 111:10, 123:18, 123:22, 123:23, 123:24, 124:9, 131:6, 132:6, 132:8, 163:2</p> <p>databases [2] - 40:1, 125:3</p> <p>dataset [2] - 125:1, 125:22</p> <p>datasets [4] - 117:6, 124:15, 164:20, 170:22</p> <p>date [14] - 25:19, 26:13, 26:22, 47:21, 49:12, 49:14, 49:25, 52:17, 70:24, 71:3, 88:4, 91:8, 171:20, 223:20</p> <p>Date [1] - 246:16</p> <p>dated [2] - 9:9, 59:2</p> <p>dating [1] - 233:24</p> <p>David [1] - 7:1</p> <p>DAVID [2] - 1:17, 2:9</p> <p>days [15] - 22:17, 25:19, 26:6, 26:15, 26:25, 28:11, 28:17, 28:22, 49:1, 143:25, 151:22, 151:24, 190:6, 190:9, 190:12</p> <p>DC [7] - 2:11, 4:7, 4:14, 4:16, 5:5, 5:12, 44:13</p> <p>De [2] - 2:4, 2:16</p> <p>DE [1] - 26:23</p> <p>DEA [135] - 7:19, 8:11, 8:18, 9:16, 10:13, 10:15, 12:4, 12:22, 13:1, 13:15, 14:23, 15:7, 15:22, 15:25, 16:3, 16:14, 16:20, 17:3, 18:9, 19:11, 19:16, 20:12, 21:6, 22:7, 24:1, 24:7, 24:14, 25:10, 25:18, 26:4, 26:18, 26:25, 27:8, 27:24, 28:3, 29:7, 30:10, 30:11, 30:14, 30:19, 31:15, 31:16, 32:12, 32:18, 33:8, 33:25, 35:7, 35:17, 35:21, 38:2, 38:4, 39:17, 43:1, 45:1, 45:3, 46:2,</p>	<p>47:2, 47:10, 47:11, 47:14, 47:16, 47:23, 47:25, 49:10, 50:10, 52:22, 53:13, 54:4, 55:3, 58:23, 59:13, 59:20, 60:17, 61:24, 62:20, 63:4, 64:17, 64:25, 65:1, 65:11, 65:12, 66:2, 66:13, 66:16, 68:8, 71:3, 71:10, 72:2, 72:3, 72:7, 72:23, 73:2, 73:12, 74:3, 75:6, 76:9, 76:17, 77:6, 77:11, 79:3, 80:1, 80:10, 80:12, 83:6, 84:5, 84:12, 84:18, 84:19, 84:21, 84:23, 84:24, 85:4, 86:9, 86:24, 87:7, 88:8, 88:10, 89:3, 89:9, 89:13, 89:24, 90:15, 91:21, 92:19, 92:21, 92:25, 93:6, 93:10, 93:11, 93:20, 94:2, 94:8</p> <p>DEA's [20] - 12:14, 13:15, 16:23, 17:20, 25:9, 33:9, 33:10, 40:5, 47:7, 56:13, 59:21, 63:1, 73:8, 73:22, 73:24, 75:19, 75:20, 75:25, 76:10, 79:9</p> <p>dead [2] - 122:18, 122:22</p> <p>deal [3] - 81:19, 109:7, 233:13</p> <p>death [100] - 100:2, 100:3, 100:4, 107:22, 121:22, 123:6, 123:7, 123:12, 123:15, 124:8, 124:21, 125:7, 125:20, 132:7, 133:16, 134:14, 134:17, 136:25, 137:1, 137:11, 143:15, 145:1, 145:16, 145:18, 146:1, 146:5, 146:18, 149:23, 149:24, 151:22, 156:7, 158:23, 158:24, 159:2, 159:4, 159:5, 159:7, 159:12, 159:16, 159:22, 160:5, 160:8, 160:9, 160:12, 160:15, 160:18, 160:22,</p>
--	---	--	--	---

<p>161:3, 164:8, 164:17, 164:18, 164:21, 165:2, 165:6, 165:8, 165:9, 165:11, 165:13, 167:6, 167:17, 167:20, 168:12, 168:19, 169:3, 169:8, 169:9, 169:17, 170:10, 170:13, 170:21, 171:24, 172:10, 172:18, 173:1, 173:3, 173:11, 174:15, 174:20, 174:24, 175:8, 175:22, 176:1, 176:12, 177:4, 177:6, 177:11, 178:19, 178:22, 179:2, 179:8, 188:16, 188:20, 189:6, 189:10, 190:6, 190:13, 218:9</p> <p>deaths [81] - 100:23, 101:2, 117:13, 120:15, 125:11, 125:13, 126:4, 126:22, 127:1, 127:7, 127:23, 128:15, 128:22, 128:25, 131:24, 132:18, 132:21, 133:2, 133:7, 134:1, 134:3, 134:5, 134:6, 134:11, 136:8, 137:13, 138:7, 138:22, 138:24, 139:3, 141:25, 142:10, 142:22, 143:1, 144:19, 146:10, 148:2, 150:13, 153:22, 153:24, 154:1, 156:16, 158:21, 163:7, 163:18, 166:14, 166:19, 167:5, 172:21, 173:8, 177:20, 179:16, 180:21, 180:22, 181:8, 181:9, 181:10, 181:23, 183:23, 190:18, 199:22, 201:4, 201:10, 203:20, 203:22, 204:2, 206:6, 214:2, 220:20, 220:21, 221:17, 221:19, 221:23, 221:24, 222:19, 222:21,</p>	<p>223:1, 223:6</p> <p>deceased [1] - 122:20</p> <p>decendent [7] - 122:25, 168:7, 170:19, 188:19, 188:25, 206:10, 208:24</p> <p>decendent's [5] - 169:22, 206:25, 207:10, 207:24, 208:6</p> <p>decedents [13] - 146:7, 146:20, 146:24, 151:19, 186:8, 187:7, 188:4, 190:4, 190:8, 190:12, 206:3, 206:15, 208:15</p> <p>deceleration [1] - 197:13</p> <p>December [4] - 47:6, 47:7, 52:18, 73:5</p> <p>decide [1] - 223:23</p> <p>decided [1] - 15:1</p> <p>decision [13] - 39:24, 39:25, 41:18, 42:14, 44:6, 44:12, 44:15, 94:15, 95:16, 167:3, 243:23, 244:22</p> <p>decisions [1] - 162:25</p> <p>decline [10] - 203:15, 204:1, 204:5, 204:12, 204:14, 205:5, 211:14, 212:18, 213:10, 213:19</p> <p>declining [1] - 211:19</p> <p>decreased [2] - 146:16, 212:9</p> <p>deems [1] - 14:20</p> <p>DEF-WV-00001 [1] - 79:15</p> <p>DEF-WV-00131 [3] - 167:9, 167:14, 167:25</p> <p>DEF-WV-00620 [1] - 40:14</p> <p>DEF-WV-01630 [3] - 174:2, 174:23, 175:15</p> <p>DEF-WV-02578 [1] - 41:22</p> <p>DEF-WV-03076 [1] - 83:8</p> <p>DEF-WV-131-A [1] - 175:23</p> <p>DEF-WV-1315 [1] - 179:24</p> <p>DEF-WV-1597 [1] - 87:24</p> <p>DEF-WV-1630 [2] -</p>	<p>176:5, 176:13</p> <p>DEF-WV-2578 [1] - 94:14</p> <p>DEF-WV-3076 [1] - 92:11</p> <p>Defendant [4] - 4:10, 5:2, 5:7, 6:2</p> <p>Defendants [3] - 1:8, 1:14, 246:7</p> <p>defendants [8] - 155:2, 156:3, 202:25, 205:11, 226:21, 236:20, 239:10, 241:10</p> <p>Defendants' [1] - 32:25</p> <p>defendants' [1] - 83:16</p> <p>defense [5] - 41:19, 58:16, 61:7, 61:13, 83:11</p> <p>deferred [1] - 104:10</p> <p>define [2] - 10:22, 184:18</p> <p>defines [1] - 72:17</p> <p>definitely [4] - 18:13, 140:23, 157:10, 235:25</p> <p>definition [2] - 10:18, 98:9</p> <p>Degree [3] - 233:22, 234:8, 234:9</p> <p>degree [9] - 103:9, 103:14, 103:15, 103:20, 103:21, 154:13, 233:21, 234:1, 234:4</p> <p>delay [1] - 119:8</p> <p>delivered [1] - 116:10</p> <p>Deloitte [1] - 236:4</p> <p>Demo [1] - 102:25</p> <p>Demo234 [1] - 228:14</p> <p>demonstrates [1] - 237:22</p> <p>demonstrating [1] - 209:25</p> <p>demonstrative [4] - 72:15, 158:12, 178:10, 199:7</p> <p>demonstratives [9] - 102:9, 102:11, 224:18, 224:20, 224:24, 225:6, 225:9, 225:15, 225:23</p> <p>Department [6] - 15:24, 16:24, 98:1, 108:17, 117:10, 148:21</p> <p>Dependence [1] -</p>	<p>108:14</p> <p>dependent [1] - 214:7</p> <p>deployed [1] - 243:6</p> <p>deposition [12] - 36:25, 37:11, 37:15, 37:18, 37:23, 39:12, 45:18, 46:9, 46:12, 91:4, 155:10, 179:14</p> <p>depth [3] - 137:6, 150:22, 151:6</p> <p>Deputy [5] - 9:6, 47:7, 56:11, 58:22, 62:25</p> <p>DEPUTY [3] - 97:7, 97:10, 97:13</p> <p>derived [1] - 158:23</p> <p>describe [6] - 88:8, 117:4, 173:18, 193:13, 196:6, 238:5</p> <p>described [8] - 124:15, 125:24, 138:17, 156:18, 159:1, 165:17, 212:20, 222:17</p> <p>describing [3] - 156:6, 237:23, 238:3</p> <p>description [2] - 33:11, 80:10</p> <p>design [2] - 72:19, 73:1</p> <p>Design [1] - 182:24</p> <p>designation [1] - 228:22</p> <p>desperation [1] - 79:5</p> <p>detail [3] - 117:18, 117:20, 235:16</p> <p>detailed [3] - 123:5, 143:17, 149:22</p> <p>details [1] - 190:24</p> <p>detect [4] - 30:13, 165:18, 166:1, 166:8</p> <p>detected [1] - 47:24</p> <p>determination [3] - 73:17, 123:10, 160:1</p> <p>determine [12] - 28:8, 120:15, 122:22, 137:6, 159:21, 160:18, 160:22, 163:17, 164:3, 166:9, 167:1, 179:2</p> <p>determined [2] - 128:10, 143:20</p> <p>determining [1] - 143:12</p> <p>Detroit [1] - 216:8</p> <p>develop [2] - 73:10, 111:22</p> <p>developed [6] - 18:20, 19:13, 19:16, 100:17, 101:15, 106:24</p>	<p>developing [1] - 111:15</p> <p>development [1] - 117:1</p> <p>Diazepam [4] - 207:5, 207:10, 207:13, 207:17</p> <p>die [1] - 189:18</p> <p>died [7] - 135:17, 136:16, 143:20, 170:3, 170:9, 183:3, 188:14</p> <p>difference [3] - 98:10, 106:10, 126:14</p> <p>differences [1] - 220:10</p> <p>different [23] - 81:17, 98:23, 99:4, 99:5, 99:24, 99:25, 111:17, 117:6, 133:22, 133:23, 145:14, 149:17, 190:11, 198:4, 198:6, 215:5, 215:12, 216:3, 216:7, 218:7, 237:20, 239:21</p> <p>difficult [6] - 160:17, 165:18, 166:1, 166:8, 166:9, 223:23</p> <p>difficulties [2] - 166:4, 166:5</p> <p>dihydrocodeine [1] - 218:20</p> <p>diligence [9] - 18:11, 18:19, 34:10, 34:24, 43:23, 82:1, 82:9, 82:11, 95:16</p> <p>DIRECT [2] - 97:19, 227:20</p> <p>direct [14] - 9:2, 25:6, 31:19, 32:10, 33:16, 41:4, 73:2, 74:21, 88:1, 88:14, 91:9, 92:13, 95:3, 103:21</p> <p>directed [2] - 83:24, 189:1</p> <p>directing [1] - 111:16</p> <p>direction [1] - 77:5</p> <p>directly [3] - 67:3, 155:19, 170:22</p> <p>Director [2] - 52:8, 228:4</p> <p>disagree [4] - 29:7, 58:2, 184:13, 188:10</p> <p>disagreed [1] - 44:1</p> <p>disagreeing [1] - 21:13</p> <p>disavow [1] - 35:21</p> <p>discipline [1] - 229:1</p>
---	---	--	---	---

<p>disciplining [1] - 178:18</p> <p>disclose [4] - 15:11, 15:25, 55:18, 72:20</p> <p>discovered [4] - 30:4, 70:1, 107:24, 178:16</p> <p>discretion [1] - 226:23</p> <p>discuss [5] - 30:11, 51:13, 72:3, 72:5</p> <p>discussed [15] - 44:14, 71:10, 72:8, 89:2, 89:8, 103:7, 119:24, 155:13, 158:22, 163:3, 166:6, 182:16, 182:21, 196:7, 201:17</p> <p>discussing [7] - 41:19, 48:25, 113:2, 136:23, 168:13, 169:11, 170:19</p> <p>discussion [1] - 44:6</p> <p>discussions [2] - 17:15, 73:23</p> <p>Disease [12] - 88:24, 89:8, 100:18, 104:10, 104:13, 104:22, 105:2, 118:1, 141:1, 143:11, 148:17, 194:12</p> <p>disease [8] - 98:12, 98:14, 100:23, 106:3, 106:11, 129:20, 160:8, 160:11</p> <p>diseases [1] - 106:4</p> <p>dismantled [1] - 180:17</p> <p>dispense [1] - 187:3</p> <p>dispensing [3] - 83:6, 93:22, 151:17</p> <p>dispute [3] - 23:16, 27:10, 185:21</p> <p>dissertation [6] - 229:20, 229:23, 229:24, 230:15, 231:14</p> <p>disservice [1] - 94:1</p> <p>dissolving [1] - 181:22</p> <p>distinctly [1] - 245:1</p> <p>distinguish [1] - 178:24</p> <p>distracting [1] - 67:2</p> <p>distribute [3] - 22:15, 47:10, 64:21</p> <p>Distribution [3] - 229:10, 230:10, 231:21</p>	<p>distribution [32] - 7:20, 8:6, 24:2, 29:10, 29:14, 66:3, 215:24, 221:10, 229:19, 230:7, 230:9, 230:13, 230:17, 231:4, 231:17, 232:7, 233:13, 233:17, 235:5, 235:8, 235:10, 235:18, 235:23, 236:5, 236:9, 236:10, 236:11, 237:6, 237:7, 237:12, 238:1, 239:8</p> <p>distributions [4] - 23:8, 64:12, 64:19, 86:11</p> <p>distributor [16] - 8:17, 15:8, 50:4, 50:7, 50:10, 52:21, 54:15, 56:12, 81:6, 236:20, 238:7, 238:24, 239:2, 239:3, 239:7, 239:10</p> <p>distributors [15] - 64:25, 162:21, 202:25, 230:1, 233:15, 236:6, 237:1, 237:15, 239:14, 240:21, 241:6, 241:10, 241:16, 241:17, 241:20</p> <p>District [2] - 7:2, 7:3</p> <p>DISTRICT [3] - 1:1, 1:1, 1:17</p> <p>Diversion [9] - 9:7, 9:13, 29:9, 47:8, 49:15, 52:9, 53:1, 53:25, 58:14</p> <p>diversion [20] - 7:19, 7:23, 30:13, 41:14, 44:8, 44:19, 61:9, 62:3, 62:9, 62:11, 64:22, 64:24, 65:1, 88:5, 88:13, 90:15, 146:9, 146:15, 221:8, 221:10</p> <p>diverted [2] - 61:8, 134:16</p> <p>diverters [1] - 147:1</p> <p>diverting [1] - 64:15</p> <p>division [1] - 234:12</p> <p>Division [3] - 52:16, 88:9, 192:4</p> <p>Doctor [144] - 99:21, 100:11, 101:3, 101:16, 102:23, 103:4, 105:9, 105:22, 106:12, 108:15, 109:3, 112:6, 114:2, 114:20, 115:23, 118:21, 120:18, 124:13, 125:7, 126:17, 129:5, 130:2, 132:24, 135:25, 139:4, 140:19, 141:9, 148:18, 149:6, 152:13, 154:12, 156:8, 156:12, 158:13, 158:21, 159:21, 160:17, 161:8, 161:17, 161:20, 162:2, 162:6, 162:12, 164:9, 164:12, 165:6, 165:17, 166:17, 166:21, 167:14, 167:17, 171:14, 172:2, 172:8, 173:1, 173:11, 173:16, 173:22, 175:15, 175:25, 176:3, 176:7, 176:12, 176:16, 176:21, 177:8, 177:9, 177:18, 177:21, 178:18, 178:22, 179:7, 179:11, 179:18, 179:24, 180:12, 180:24, 181:1, 181:13, 182:16, 183:5, 183:13, 183:22, 184:4, 184:11, 185:4, 185:13, 185:25, 186:4, 186:6, 186:11, 186:25, 187:3, 187:16, 187:25, 188:8, 188:17, 189:7, 189:19, 190:4, 190:23, 191:4, 191:8, 192:20, 192:23, 193:2, 193:9, 193:15, 193:18, 193:25, 194:4, 194:14, 194:21, 195:3, 195:16, 195:24, 196:1, 196:5, 196:11, 197:1, 197:18, 198:8, 199:10, 199:20, 199:23, 199:25, 200:6,</p>	<p>201:8, 201:11, 201:16, 202:11, 202:25, 203:14, 204:13, 205:9, 209:12, 213:12, 219:25, 221:13, 221:16, 222:8, 222:14, 224:7, 244:7</p> <p>doctor [9] - 107:10, 146:11, 146:12, 146:19, 162:13, 187:4, 187:9, 189:1</p> <p>doctoral [1] - 127:5</p> <p>doctors [8] - 40:10, 40:17, 93:7, 94:12, 146:13, 162:21, 212:19, 213:11</p> <p>Document [1] - 20:1</p> <p>document [85] - 9:1, 9:3, 11:14, 11:18, 11:19, 17:25, 28:3, 28:5, 30:8, 31:23, 41:23, 45:22, 46:4, 46:25, 48:6, 48:21, 49:18, 49:20, 51:21, 52:17, 58:9, 59:20, 59:24, 60:8, 63:19, 65:9, 68:7, 68:15, 68:18, 68:20, 68:21, 68:23, 69:3, 70:10, 70:13, 70:16, 70:18, 70:20, 71:14, 71:21, 74:18, 74:22, 76:20, 76:23, 80:19, 85:24, 86:23, 87:3, 87:20, 92:10, 92:12, 111:14, 127:12, 150:4, 150:5, 150:7, 168:2, 168:6, 168:10, 169:6, 169:21, 171:9, 171:14, 171:19, 172:5, 173:15, 173:24, 174:3, 174:22, 176:3, 176:4, 176:14, 176:24, 179:19, 179:24, 180:3, 180:6, 180:8, 180:10, 180:11, 186:4, 193:15, 196:9, 205:14, 215:19</p> <p>documentary [1] - 55:8</p> <p>documentation [3] - 85:22, 241:13, 241:14</p> <p>documented [4] - 142:8, 148:12,</p>	<p>151:19, 186:8</p> <p>documents [13] - 55:8, 67:9, 67:10, 142:6, 177:11, 179:4, 219:21, 224:10, 241:21, 241:23, 242:17, 242:19</p> <p>done [32] - 15:2, 36:5, 36:7, 58:13, 67:6, 81:24, 88:25, 96:2, 109:16, 109:23, 113:4, 113:5, 113:17, 123:6, 124:3, 126:19, 128:13, 141:9, 142:8, 146:4, 148:10, 148:16, 149:13, 163:24, 185:19, 192:15, 192:16, 193:7, 198:21, 199:1, 202:7, 236:4</p> <p>door [1] - 80:7</p> <p>doubt [1] - 56:20</p> <p>Douglas [1] - 4:17</p> <p>down [47] - 15:3, 23:23, 24:2, 26:9, 38:2, 39:24, 59:5, 62:6, 65:9, 73:20, 79:21, 83:18, 87:6, 88:5, 91:14, 98:25, 105:6, 105:17, 108:17, 111:20, 112:19, 112:20, 113:24, 115:4, 128:21, 129:14, 131:1, 137:20, 141:21, 147:17, 151:1, 171:23, 172:4, 172:17, 173:15, 176:8, 180:14, 182:9, 210:1, 210:2, 210:23, 215:9, 215:10, 215:14, 218:8, 243:17</p> <p>downs [2] - 204:24</p> <p>downstream [1] - 239:16</p> <p>Dr [52] - 97:5, 97:21, 101:19, 102:17, 103:1, 114:6, 114:11, 114:17, 119:3, 119:16, 119:20, 122:9, 135:10, 140:1, 153:14, 155:3, 155:8, 178:9, 182:9, 192:3, 205:21,</p>
---	---	--	--

<p>224:8, 224:12, 225:4, 226:8, 226:10, 226:20, 227:11, 227:12, 227:22, 228:1, 228:7, 228:16, 229:11, 231:6, 232:10, 233:9, 233:18, 234:17, 234:23, 235:5, 236:13, 236:19, 237:3, 239:9, 242:15, 243:9, 243:17, 243:23, 244:4, 244:6, 244:14</p> <p>DR [1] - 97:12</p> <p>Dracunculiasis [1] - 105:2</p> <p>dramatic [4] - 136:13, 139:1, 139:9, 204:10</p> <p>dramatically [2] - 130:10, 221:25</p> <p>draw [2] - 150:9, 220:15</p> <p>drawing [2] - 243:21, 243:23</p> <p>drew [1] - 84:8</p> <p>drinking [1] - 99:13</p> <p>Drive [1] - 6:15</p> <p>driven [2] - 130:16, 230:6</p> <p>driving [4] - 220:6, 223:25, 224:2, 224:3</p> <p>drop [2] - 215:9, 215:14</p> <p>drove [1] - 158:15</p> <p>Drug [10] - 6:2, 108:14, 110:20, 143:21, 150:2, 151:13, 180:3, 191:5, 221:7, 246:7</p> <p>drug [115] - 61:9, 99:17, 99:22, 100:5, 100:7, 100:12, 100:19, 101:2, 106:23, 109:8, 109:14, 109:21, 110:10, 110:11, 110:18, 111:8, 112:2, 113:10, 114:8, 114:13, 115:6, 115:13, 117:12, 117:25, 118:7, 118:8, 118:11, 118:14, 118:18, 118:19, 122:1, 123:11, 125:6, 126:6, 126:14, 127:4, 127:8, 127:23,</p>	<p>128:11, 129:1, 130:4, 130:7, 130:12, 130:16, 132:6, 132:18, 132:21, 133:1, 134:12, 134:20, 134:21, 135:17, 137:7, 137:8, 141:11, 142:23, 143:12, 144:12, 144:19, 144:21, 147:1, 147:23, 148:2, 148:13, 152:15, 153:19, 153:21, 154:6, 155:22, 156:19, 156:24, 159:14, 162:15, 163:13, 163:14, 166:10, 172:23, 177:25, 181:11, 183:11, 183:23, 185:11, 189:4, 189:6, 189:9, 189:15, 190:2, 192:25, 194:25, 195:22, 197:8, 197:13, 198:2, 198:9, 198:19, 198:20, 203:20, 203:22, 204:1, 206:6, 210:15, 210:16, 211:18, 216:7, 216:8, 216:10, 218:2, 218:6, 219:15, 220:21, 221:7</p> <p>DRUG [2] - 1:7, 1:13</p> <p>drug-related [3] - 156:19, 156:24</p> <p>drugs [86] - 21:6, 61:8, 62:5, 68:12, 69:7, 99:19, 100:22, 109:22, 110:1, 110:9, 111:10, 120:15, 123:13, 125:12, 126:15, 131:25, 133:16, 133:19, 133:20, 133:21, 134:19, 142:19, 144:18, 144:20, 146:25, 147:6, 149:23, 152:17, 152:18, 152:20, 153:20, 154:1, 154:2, 154:7, 156:6, 158:18, 159:6, 160:4, 160:7, 160:13, 160:14, 160:16, 160:18, 160:24, 161:2, 161:25, 162:5,</p>	<p>164:18, 172:24, 183:15, 184:7, 184:8, 184:10, 185:9, 188:3, 188:5, 188:6, 188:7, 188:15, 193:17, 193:21, 194:25, 195:5, 195:20, 196:11, 201:2, 201:17, 206:2, 206:14, 210:16, 210:17, 210:20, 210:24, 211:3, 211:25, 215:12, 216:21, 216:24, 220:7, 220:12, 220:22</p> <p>drugstore [3] - 81:17, 81:18, 81:21</p> <p>due [21] - 15:1, 16:1, 16:3, 16:4, 16:5, 16:6, 18:11, 18:19, 34:9, 34:24, 43:23, 82:1, 82:9, 82:11, 95:16, 131:25, 137:7, 137:23, 152:17, 190:19, 194:25</p> <p>Dunedin [1] - 103:16</p> <p>duo [1] - 209:14</p> <p>during [41] - 7:22, 9:2, 30:4, 33:14, 35:8, 44:20, 45:24, 46:20, 47:20, 53:24, 58:13, 58:23, 62:18, 67:5, 67:6, 68:8, 69:22, 69:23, 69:25, 75:8, 79:8, 89:18, 136:14, 138:8, 144:13, 147:8, 147:13, 173:7, 179:13, 179:16, 181:7, 181:17, 182:9, 182:21, 201:16, 204:5, 218:3, 221:9, 233:7, 234:13, 243:18</p> <p>During [2] - 20:12, 230:24</p> <p>duty [2] - 43:22, 44:11</p> <p>dying [2] - 99:17, 144:17</p> <p>dyke [1] - 107:13</p> <p>dynamic [1] - 209:14</p> <p>Dynamics [1] - 191:5</p>	<p>e-mail [4] - 49:5, 49:8, 49:10, 49:12</p> <p>eager [1] - 119:12</p> <p>early [11] - 36:12, 55:3, 56:13, 62:13, 116:3, 126:9, 137:22, 140:25, 144:14, 156:9, 181:2</p> <p>ease [2] - 165:24, 176:1</p> <p>easier [4] - 128:14, 178:8, 199:25, 200:1</p> <p>easiest [1] - 158:10</p> <p>East [3] - 3:5, 3:12, 4:18</p> <p>eat [1] - 164:24</p> <p>Ebola [1] - 104:16</p> <p>economic [1] - 214:11</p> <p>editorial [1] - 233:9</p> <p>Editorial [1] - 233:11</p> <p>educate [4] - 64:25, 65:2, 240:5, 240:7</p> <p>education [3] - 105:9, 105:12, 105:23</p> <p>educational [2] - 103:6, 103:8</p> <p>effect [7] - 26:12, 26:14, 28:17, 28:19, 28:22, 42:7, 42:9</p> <p>effective [3] - 26:13, 44:7, 47:21</p> <p>effects [1] - 184:8</p> <p>efficiencies [5] - 237:12, 237:19, 237:23, 238:1, 239:5</p> <p>effort [3] - 117:11, 166:25, 232:3</p> <p>Effort [1] - 108:12</p> <p>efforts [5] - 64:25, 65:1, 109:13, 229:25, 231:4</p> <p>egg [1] - 244:16</p> <p>eight [4] - 110:21, 111:21, 201:6, 235:2</p> <p>Eighth [1] - 3:10</p> <p>either [7] - 26:15, 27:21, 28:25, 30:16, 78:12, 205:11, 233:17</p> <p>elective [1] - 229:7</p> <p>electronic [1] - 25:21</p> <p>elements [2] - 72:12, 72:13</p> <p>elicit [2] - 170:4, 213:7</p> <p>eliciting [1] - 213:4</p> <p>ELIZABETH [1] - 6:14</p> <p>email [3] - 14:18, 15:21, 22:2</p> <p>emergence [1] - 202:15</p>	<p>Emergency [1] - 101:5</p> <p>emphasizing [1] - 216:16</p> <p>empirical [1] - 231:23</p> <p>employ [1] - 76:9</p> <p>employed [1] - 228:1</p> <p>employee [3] - 75:8, 192:4, 221:11</p> <p>empty [1] - 168:18</p> <p>EMT [1] - 122:19</p> <p>Encino [1] - 3:18</p> <p>encompass [1] - 145:3</p> <p>encompasses [1] - 10:19</p> <p>end [8] - 31:19, 67:25, 94:17, 121:5, 127:8, 184:3, 219:15, 239:18</p> <p>ended [1] - 17:4</p> <p>endoscopies [1] - 203:8</p> <p>endowed [4] - 98:3, 108:24, 109:3, 232:17</p> <p>enforcement [9] - 15:13, 36:25, 37:4, 38:22, 177:14, 179:8, 180:16, 180:19, 181:25</p> <p>Enforcement [2] - 180:4, 221:7</p> <p>engage [4] - 237:1, 238:10, 240:2, 242:19</p> <p>engaged [4] - 109:17, 236:21, 241:7, 241:11</p> <p>engaging [3] - 12:7, 43:13, 94:24</p> <p>English [1] - 29:13</p> <p>enjoy [1] - 105:19</p> <p>enormous [1] - 84:25</p> <p>ensure [5] - 27:20, 38:25, 81:8, 81:23, 93:21</p> <p>enter [2] - 123:17, 124:9</p> <p>entered [5] - 24:7, 32:18, 45:2, 47:1, 149:3</p> <p>entire [5] - 46:3, 100:6, 145:6, 181:10, 216:9</p> <p>entirely [3] - 167:2, 216:18, 216:22</p> <p>entities [1] - 57:8</p> <p>entitled [4] - 16:3, 60:23, 80:6, 144:2</p> <p>entity [1] - 47:9</p>
--	---	---	--	--

E

E-commerce [3] -
9:16, 9:17, 14:15

<p>entry [1] - 33:10 ENU [1] - 4:12 eon [1] - 230:20 Epidemic [2] - 104:14, 191:5 epidemic [8] - 124:5, 137:23, 154:16, 197:8, 197:16, 210:4, 215:3, 218:1 epidemic's [1] - 126:1 epidemiological [1] - 185:18 epidemiologist [13] - 97:23, 98:2, 98:7, 101:23, 103:5, 115:8, 116:19, 139:8, 145:8, 162:8, 164:22, 186:23, 223:12 epidemiologists [6] - 100:13, 121:15, 125:17, 125:19, 148:17, 162:24 Epidemiology [5] - 98:1, 98:3, 108:12, 108:16, 108:18 epidemiology [22] - 98:5, 98:6, 98:8, 98:18, 99:21, 99:23, 104:8, 106:4, 106:5, 106:6, 107:16, 107:17, 108:10, 110:10, 112:11, 114:8, 114:12, 120:19, 149:8, 192:8, 210:10 episodes [1] - 216:23 equivalency [1] - 103:24 equivalent [1] - 103:21 especially [1] - 232:8 essence [1] - 242:22 essential [4] - 79:3, 113:12, 116:4, 126:7 essentially [3] - 13:2, 104:15, 233:1 establish [5] - 53:11, 56:7, 56:20, 82:13, 205:3 et [4] - 1:7, 1:13, 246:6, 246:7 Europeans [1] - 107:24 evaluate [6] - 144:16, 162:14, 162:22, 238:17, 241:5, 241:6 event [1] - 177:4 events [1] - 178:6 everywhere [1] -</p>	<p>130:21 evidence [35] - 8:21, 20:3, 31:25, 32:25, 48:7, 55:8, 60:7, 79:14, 102:17, 115:1, 137:12, 140:6, 143:6, 146:11, 153:19, 157:9, 169:18, 170:13, 175:1, 175:11, 197:24, 198:16, 215:19, 218:19, 220:11, 224:11, 224:13, 224:15, 224:19, 225:5, 225:15, 241:12, 241:14, 241:18, 243:5 evidentiary [1] - 225:24 evolution [1] - 115:10 evolved [2] - 44:20, 214:4 exact [10] - 23:13, 23:18, 76:19, 81:19, 116:20, 139:9, 149:21, 160:10, 166:24, 167:7 exactly [35] - 11:22, 69:22, 98:20, 104:18, 105:24, 112:12, 120:21, 121:17, 124:3, 125:14, 125:19, 127:19, 127:24, 130:14, 131:3, 131:4, 131:10, 131:22, 132:2, 133:18, 135:20, 138:5, 138:15, 142:16, 145:5, 145:23, 147:20, 148:4, 149:12, 149:24, 151:15, 152:9, 153:2, 176:6, 188:25 Exactly [2] - 211:6, 212:15 exaggerated [1] - 94:2 exam [2] - 48:8, 103:24 examination [7] - 7:7, 9:2, 32:11, 41:5, 46:6, 95:4, 182:21 EXAMINATION [8] - 85:13, 97:19, 155:6, 205:19, 209:10, 219:23, 222:12, 227:20 examine [1] - 185:2</p>	<p>examined [1] - 212:25 examiner [3] - 189:3, 189:11, 218:25 Examiner [21] - 110:5, 113:16, 121:21, 122:23, 123:6, 134:13, 137:6, 150:21, 151:6, 159:11, 159:14, 159:15, 159:25, 160:4, 160:14, 160:18, 161:9, 167:18, 169:21, 170:20, 176:23 examiner's [1] - 218:10 Examiner's [4] - 111:9, 143:17, 150:1, 166:25 examiners [1] - 122:24 Examiners [1] - 161:15 examining [1] - 142:2 example [12] - 11:9, 98:17, 98:20, 99:14, 99:16, 168:12, 169:17, 170:17, 174:18, 181:18, 233:16, 237:11 exceeded [1] - 138:7 excels [1] - 228:24 except [2] - 24:4, 124:3 exception [5] - 34:11, 34:25, 77:15, 77:21, 77:25 excerpt [2] - 36:24, 37:10 excerpts [1] - 59:24 Excessive [6] - 49:1, 53:1, 53:4, 54:13, 55:4, 56:14 exchanges [1] - 91:4 excited [1] - 105:19 excuse [5] - 69:15, 154:9, 223:4, 226:13, 243:10 excused [3] - 96:1, 96:20, 96:22 exec [1] - 76:12 execs [1] - 53:24 execute [2] - 93:6, 240:14 Executive [2] - 74:9, 150:10 exemplar [2] - 168:17, 169:2 exempt [1] - 82:4 exempted [3] - 79:17,</p>	<p>81:5, 82:23 exemption [1] - 80:2 Exhibit [24] - 8:20, 122:6, 132:12, 136:17, 140:16, 178:15, 186:3, 199:5, 199:7, 199:10, 199:14, 199:18, 200:1, 200:6, 200:8, 200:12, 201:6, 201:23, 203:11, 205:18, 205:23, 225:1, 225:2 exhibit [9] - 8:20, 20:1, 32:24, 45:17, 83:11, 102:17, 129:5, 149:4, 174:11 exhibits [1] - 224:22 existed [1] - 179:11 exists [1] - 240:3 expect [4] - 63:8, 71:10, 72:3, 188:20 expected [2] - 63:15, 72:6 experience [8] - 61:23, 64:10, 100:11, 108:3, 113:14, 230:7, 230:13 experienced [3] - 144:12, 147:13, 190:6 expert [18] - 36:24, 37:11, 39:11, 114:3, 114:7, 114:12, 114:17, 161:6, 166:3, 205:24, 211:24, 234:18, 234:24, 236:13, 242:15, 242:16, 242:24, 242:25 experts [7] - 164:22, 164:25, 165:1, 165:15, 192:8, 199:16, 236:3 explain [23] - 7:23, 7:25, 38:14, 62:1, 64:18, 80:6, 80:18, 80:20, 81:4, 82:23, 86:10, 118:8, 122:3, 122:16, 126:18, 129:8, 133:13, 136:8, 136:18, 138:12, 140:9, 142:17, 183:21 explained [5] - 10:7, 12:25, 73:6, 89:11, 95:6 explaining [1] -</p>	<p>127:22 explains [1] - 133:4 explored [2] - 46:5, 46:19 exponential [16] - 193:13, 193:23, 196:6, 196:16, 196:21, 197:10, 197:14, 197:21, 197:24, 198:3, 198:9, 198:17, 198:18, 210:11, 216:13, 216:16 exponentially [1] - 192:25 exposure [1] - 146:25 extended [1] - 138:16 extensively [1] - 225:18 extent [4] - 21:8, 62:11, 109:22, 112:21 external [2] - 242:1, 243:1 External [1] - 242:2 extra [1] - 83:15 extract [1] - 128:14 extracted [1] - 165:16 extraordinarily [1] - 64:12 extremely [7] - 28:11, 84:4, 84:20, 92:20, 93:1, 93:13, 94:11 eye [2] - 39:5, 206:18</p>
F				
<p>Faber [2] - 7:1, 168:6 FABER [1] - 1:17 face [1] - 53:12 facilitate [1] - 10:15 facilitating [1] - 11:1 facilitation [1] - 10:20 facilities [2] - 7:23, 7:24 facility [8] - 7:25, 8:1, 22:8, 22:12, 22:22, 22:25, 23:6, 24:1 fact [30] - 11:14, 13:14, 16:15, 18:20, 19:21, 24:13, 25:8, 27:4, 59:20, 60:2, 60:12, 70:18, 80:11, 82:9, 100:15, 100:20, 108:21, 113:6, 114:12, 145:10, 160:3, 160:21, 161:23, 166:8, 178:11, 186:23, 198:8,</p>				

<p>211:13, 233:4, 234:24</p> <p>factor [3] - 160:15, 189:24, 190:1</p> <p>factors [12] - 98:13, 99:15, 99:17, 100:2, 100:3, 159:2, 159:8, 159:15, 159:18, 212:8, 214:9, 214:11</p> <p>failed [2] - 48:18, 224:10</p> <p>failing [1] - 87:14</p> <p>failure [1] - 66:7</p> <p>Fair [2] - 13:20, 192:17</p> <p>fair [3] - 21:22, 110:18, 131:17</p> <p>fairly [1] - 195:1</p> <p>faith [1] - 56:5</p> <p>faithfully [1] - 93:6</p> <p>fall [1] - 241:20</p> <p>falls [1] - 173:7</p> <p>familiar [24] - 50:18, 66:6, 78:25, 113:1, 113:18, 120:5, 120:8, 120:11, 121:20, 121:24, 141:25, 145:7, 145:10, 148:20, 148:25, 149:7, 191:16, 212:10, 212:14, 212:18, 213:10, 235:5, 235:8, 235:19</p> <p>familiarize [1] - 235:22</p> <p>family [6] - 61:10, 88:18, 219:5, 219:7, 219:10, 219:11</p> <p>Family [1] - 236:10</p> <p>famous [2] - 154:5, 232:16</p> <p>fancy [1] - 104:14</p> <p>fancy-sounding [1] - 104:14</p> <p>far [7] - 24:15, 35:12, 107:24, 112:18, 116:25, 118:20, 241:5</p> <p>farm [1] - 164:24</p> <p>FARRELL [23] - 2:3, 96:16, 119:12, 169:24, 170:12, 174:12, 175:5, 209:11, 209:21, 209:23, 210:25, 211:2, 212:3, 212:6, 213:16, 214:18, 214:21, 214:22, 215:22, 219:20,</p>	<p>244:2, 244:14, 244:19</p> <p>Farrell [13] - 2:4, 2:15, 119:11, 169:23, 209:8, 212:2, 213:7, 214:13, 214:15, 214:20, 215:18, 215:20, 244:18</p> <p>fascinating [1] - 108:2</p> <p>fast [2] - 106:13, 108:6</p> <p>fatal [23] - 117:9, 123:14, 139:22, 139:23, 161:23, 163:4, 165:19, 166:21, 188:5, 188:6, 188:7, 196:12, 196:15, 200:9, 200:12, 200:16, 201:7, 201:23, 202:2, 202:12, 202:17, 202:21, 203:16</p> <p>Fatalities [2] - 144:3, 220:15</p> <p>fatalities [9] - 122:1, 125:4, 125:5, 128:11, 128:12, 142:2, 148:24, 153:5, 153:16</p> <p>Fatality [2] - 150:5, 186:2</p> <p>fatality [1] - 122:16</p> <p>FCRR [1] - 6:18</p> <p>FDA [1] - 177:25</p> <p>feature [1] - 148:14</p> <p>February [1] - 47:6</p> <p>federal [1] - 109:4</p> <p>Federal [2] - 41:17, 216:6</p> <p>federally [1] - 111:13</p> <p>feeds [2] - 170:21, 172:10</p> <p>feelings [1] - 90:10</p> <p>Feinberg [1] - 109:11</p> <p>felt [8] - 123:13, 125:25, 126:20, 127:11, 134:13, 137:14, 149:13, 150:20</p> <p>female [1] - 215:5</p> <p>females [2] - 151:23, 152:12</p> <p>fentanyl [47] - 138:25, 139:1, 140:20, 140:21, 140:23, 140:24, 141:5, 141:6, 141:8, 153:6, 154:7, 158:14, 164:14, 177:20, 177:21, 177:24,</p>	<p>178:1, 178:4, 178:12, 178:16, 178:19, 178:24, 178:25, 179:3, 179:11, 179:25, 180:12, 180:17, 180:22, 181:2, 181:17, 181:21, 182:2, 201:20, 202:15, 202:20, 203:2, 211:16, 211:19, 214:8, 220:2, 220:6, 222:23, 223:25</p> <p>fentanyl-related [3] - 177:20, 178:12, 180:22</p> <p>few [27] - 16:7, 22:12, 52:9, 61:6, 78:5, 85:1, 85:15, 85:22, 102:8, 116:3, 118:12, 122:11, 126:4, 126:22, 126:24, 128:19, 133:6, 140:25, 155:12, 164:13, 178:16, 187:12, 199:3, 206:17, 216:24, 226:19, 241:12</p> <p>fewer [1] - 158:1</p> <p>Field [2] - 52:16, 88:9</p> <p>field [11] - 99:23, 107:16, 108:3, 110:20, 111:20, 120:19, 120:23, 192:8, 234:24, 242:15, 242:24</p> <p>figure [4] - 23:13, 139:7, 139:9, 244:13</p> <p>Figure [7] - 141:17, 158:9, 158:19, 159:9, 159:19, 178:9, 178:11</p> <p>figures [1] - 197:25</p> <p>file [1] - 63:21</p> <p>filed [2] - 165:11, 244:1</p> <p>filled [4] - 151:25, 187:9, 190:5, 190:12</p> <p>final [3] - 43:11, 43:21, 223:20</p> <p>finally [1] - 108:23</p> <p>financing [1] - 236:9</p> <p>findings [9] - 116:8, 116:12, 128:3, 138:13, 150:18, 151:9, 153:2, 185:14, 185:21</p> <p>fine [9] - 19:18, 24:10,</p>	<p>24:14, 24:15, 68:22, 78:4, 169:3, 169:9</p> <p>finger [1] - 107:12</p> <p>finish [4] - 77:12, 121:3, 138:11, 209:9</p> <p>finished [1] - 96:20</p> <p>firm [3] - 57:8, 57:9, 127:12</p> <p>Firm [2] - 3:4, 3:7</p> <p>First [1] - 240:25</p> <p>first [41] - 10:2, 18:6, 25:16, 29:4, 34:8, 35:23, 38:2, 42:5, 42:22, 45:23, 47:1, 72:18, 92:18, 98:7, 103:8, 106:20, 111:3, 113:3, 117:5, 117:7, 121:10, 121:19, 125:22, 131:12, 132:13, 133:25, 135:7, 147:11, 148:12, 176:10, 178:12, 178:14, 178:19, 179:25, 185:1, 192:18, 193:3, 217:10, 218:11, 220:1</p> <p>fit [2] - 196:20, 197:20</p> <p>five [13] - 26:12, 27:2, 27:11, 28:17, 28:19, 29:9, 87:5, 118:15, 119:2, 127:1, 133:23, 146:18, 201:17</p> <p>five-year [1] - 27:2</p> <p>FL [1] - 2:14</p> <p>flag [2] - 243:24, 244:3</p> <p>Flaherty [1] - 5:14</p> <p>FLAHIVE [1] - 5:10</p> <p>flat [5] - 130:8, 138:21, 194:12, 194:13, 216:15</p> <p>flattening [1] - 138:18</p> <p>flexibility [1] - 73:16</p> <p>flies [1] - 112:19</p> <p>flip [2] - 39:9, 218:16</p> <p>Floor [1] - 3:5</p> <p>Florida [1] - 62:6</p> <p>flunked [1] - 29:14</p> <p>fly [1] - 108:2</p> <p>flying [1] - 67:10</p> <p>focus [7] - 46:4, 118:17, 127:18, 215:8, 229:17, 230:2, 230:4</p> <p>focused [3] - 114:22, 177:18, 232:6</p> <p>follow [4] - 30:19, 48:18, 73:4, 196:18</p>	<p>followed [4] - 13:1, 13:15, 117:2, 131:20</p> <p>following [4] - 17:13, 20:8, 25:19, 133:15</p> <p>follows [5] - 7:4, 149:15, 156:2, 195:22, 196:16</p> <p>food [1] - 164:24</p> <p>Footnote [1] - 192:2</p> <p>footprint [1] - 234:11</p> <p>FOR [1] - 1:1</p> <p>force [2] - 26:12, 26:14</p> <p>foregoing [1] - 246:4</p> <p>forensic [2] - 111:8, 123:9</p> <p>forged [1] - 221:11</p> <p>forget [1] - 73:21</p> <p>form [10] - 19:12, 19:16, 19:20, 155:17, 163:18, 164:11, 173:3, 201:19, 203:11, 241:9</p> <p>formal [1] - 106:20</p> <p>format [2] - 13:22, 25:21</p> <p>formed [3] - 141:10, 165:3, 241:21</p> <p>former [2] - 127:5, 162:9</p> <p>forming [6] - 164:16, 173:12, 177:9, 179:9, 181:15, 240:25</p> <p>forms [2] - 177:22, 178:1</p> <p>Fort [1] - 234:14</p> <p>forth [3] - 48:1, 174:20, 185:22</p> <p>fortunate [1] - 107:16</p> <p>forward [5] - 90:6, 108:6, 117:2, 119:9, 158:6</p> <p>foundation [18] - 43:24, 45:25, 46:14, 54:16, 55:6, 55:24, 69:8, 69:11, 70:17, 70:19, 74:5, 77:19, 79:24, 80:20, 82:20, 102:10, 225:13, 225:16</p> <p>Foundation [1] - 236:10</p> <p>four [9] - 23:11, 23:15, 23:21, 194:3, 194:6, 195:2, 195:9, 198:10, 202:3</p> <p>four-year [1] - 202:3</p> <p>fraction [5] - 84:20,</p>
--	---	--	---	---

<p>92:20, 93:1, 93:13, 94:12</p> <p>frameworks [3] - 235:11, 237:10, 237:11</p> <p>frank [1] - 192:12</p> <p>free [3] - 88:18, 96:5, 185:9</p> <p>frequent [1] - 88:16</p> <p>frequently [1] - 8:12</p> <p>friend [2] - 185:10, 185:11</p> <p>friends [4] - 61:10, 88:18, 202:9, 221:2</p> <p>front [9] - 33:2, 52:1, 68:22, 69:3, 80:19, 167:14, 171:14, 175:16, 210:1</p> <p>fulfill [1] - 10:21</p> <p>full [12] - 26:12, 26:14, 29:4, 42:22, 58:19, 58:21, 59:6, 59:12, 91:16, 97:8, 185:1, 195:19</p> <p>Fuller [2] - 2:4, 2:15</p> <p>FULLER [1] - 2:15</p> <p>function [2] - 7:25, 240:5</p> <p>functionality [1] - 29:8</p> <p>fundamental [1] - 43:3</p> <p>funded [3] - 110:19, 111:13, 230:16</p> <p>funding [2] - 111:21, 111:25</p> <p>funny [1] - 103:10</p>	<p>generic [7] - 65:13, 66:3, 66:7, 68:12, 69:7, 70:2, 151:12</p> <p>genuinely [1] - 137:14</p> <p>genus [1] - 219:4</p> <p>geo [1] - 218:2</p> <p>geo-spatial [1] - 218:2</p> <p>geographic [4] - 115:17, 115:23, 115:25, 220:10</p> <p>Gina [21] - 37:20, 83:25, 122:6, 126:10, 128:6, 129:2, 131:11, 135:7, 135:23, 136:17, 137:16, 138:1, 140:16, 141:18, 144:7, 144:22, 147:7, 149:1, 151:1, 152:3, 220:23</p> <p>gist [1] - 29:6</p> <p>given [13] - 33:8, 58:25, 59:7, 59:13, 60:20, 65:6, 108:24, 111:21, 154:12, 168:10, 171:9, 198:23, 234:15</p> <p>glad [1] - 239:22</p> <p>goal [1] - 240:18</p> <p>gold [1] - 108:25</p> <p>goods [1] - 239:4</p> <p>Gordon [4] - 97:5, 97:9, 97:23, 114:7</p> <p>GORDON [1] - 97:12</p> <p>Gordon's [1] - 102:17</p> <p>Governance [1] - 231:22</p> <p>government [10] - 45:10, 77:21, 77:23, 77:25, 90:12, 90:13, 90:19, 90:22, 150:5, 231:24</p> <p>Government [3] - 90:4, 90:7, 216:6</p> <p>government's [1] - 90:21</p> <p>graduated [1] - 234:15</p> <p>grant [2] - 110:3, 111:5</p> <p>graph [12] - 128:10, 131:21, 133:4, 141:13, 193:24, 194:2, 194:13, 195:6, 196:7, 196:17, 196:21, 198:24</p> <p>graphics [1] - 135:3</p> <p>graphs [5] - 116:11, 130:3, 217:16,</p>	<p>224:14, 225:13</p> <p>Great [1] - 105:6</p> <p>great [4] - 120:4, 124:5, 179:18, 195:18</p> <p>greater [1] - 204:6</p> <p>greatest [1] - 146:15</p> <p>GRETCHEN [1] - 6:7</p> <p>grew [2] - 192:25, 234:10</p> <p>grid [2] - 215:13, 215:23</p> <p>grind [1] - 119:4</p> <p>ground [1] - 239:7</p> <p>grounds [1] - 51:1</p> <p>group [14] - 100:16, 101:1, 118:13, 146:16, 147:16, 148:16, 149:11, 157:5, 157:6, 157:7, 157:11, 157:12, 158:5, 210:17</p> <p>grouped [1] - 126:24</p> <p>grouping [3] - 126:5, 126:8, 127:3</p> <p>groups [1] - 146:22</p> <p>growth [9] - 193:13, 193:23, 195:20, 196:6, 197:10, 197:14, 197:15, 210:3, 216:16</p> <p>guess [5] - 13:13, 19:25, 27:2, 35:12, 36:14</p> <p>guidance [20] - 32:12, 35:5, 42:19, 47:14, 47:25, 48:18, 50:10, 52:22, 54:12, 54:14, 54:20, 56:22, 73:23, 73:24, 74:4, 75:20, 75:25, 76:11, 77:10</p> <p>guide [2] - 179:25, 220:1</p> <p>Guinea [3] - 105:2, 107:9, 107:18</p>	<p>32:24, 97:11, 116:14, 129:6, 167:10, 171:19, 180:10, 180:15, 187:19, 193:24, 195:18, 196:25, 210:9, 211:8, 218:17, 227:17, 238:6, 238:12, 238:22</p> <p>hand-out [1] - 32:24</p> <p>handed [7] - 20:1, 46:10, 46:11, 58:10, 103:1, 179:24, 191:4</p> <p>handing [1] - 19:2</p> <p>handle [3] - 99:12, 106:9, 126:8</p> <p>handled [1] - 125:16</p> <p>happy [5] - 59:22, 83:16, 169:7, 169:12, 181:13</p> <p>hard [5] - 112:4, 121:3, 124:23, 130:20, 168:19</p> <p>HARDIN [1] - 5:3</p> <p>harm [1] - 84:25</p> <p>Harvard [6] - 101:10, 104:6, 104:12, 105:13, 105:18, 107:5</p> <p>Hawkins [2] - 3:7, 57:18</p> <p>HDMA [4] - 78:24, 78:25, 79:1, 79:2</p> <p>head [2] - 102:1, 102:2</p> <p>headache [1] - 121:5</p> <p>heading [3] - 83:24, 84:1, 197:4</p> <p>headline [1] - 84:6</p> <p>headquarters [2] - 25:19, 30:11</p> <p>heads [1] - 243:16</p> <p>Health [23] - 4:11, 5:2, 97:24, 98:4, 100:16, 101:11, 101:12, 104:5, 104:6, 104:12, 105:13, 105:18, 106:21, 107:6, 108:13, 108:18, 117:10, 117:16, 118:3, 123:16, 124:12, 148:21, 205:22</p> <p>health [18] - 97:23, 98:5, 98:16, 99:14, 100:1, 104:8, 105:23, 105:24, 106:1, 106:5, 106:7, 106:9, 107:7, 107:8, 108:10, 112:16,</p>	<p>122:24</p> <p>healthcare [5] - 93:5, 93:12, 221:11, 236:5, 236:6</p> <p>hear [2] - 67:8, 205:4</p> <p>heard [4] - 33:25, 69:18, 148:19, 169:4</p> <p>hearing [2] - 65:7, 119:9</p> <p>hearsay [22] - 50:25, 54:17, 55:6, 55:9, 55:23, 56:18, 56:25, 59:15, 59:16, 74:5, 74:25, 75:12, 75:21, 76:1, 77:13, 77:15, 77:20, 77:23, 78:1, 78:7</p> <p>heartland [1] - 60:19</p> <p>held [1] - 30:22</p> <p>Hello [1] - 227:23</p> <p>help [3] - 101:20, 104:18, 139:11</p> <p>helpful [3] - 139:13, 140:8, 226:12</p> <p>helps [1] - 225:3</p> <p>heroin [46] - 136:1, 136:4, 136:5, 136:9, 136:11, 136:15, 137:1, 137:5, 137:7, 137:8, 137:10, 137:13, 138:23, 141:3, 153:6, 153:23, 154:1, 158:14, 164:14, 165:18, 165:21, 166:11, 166:14, 166:22, 167:5, 170:6, 173:8, 176:20, 177:1, 177:9, 177:15, 201:14, 201:19, 201:20, 202:11, 202:16, 203:2, 211:19, 213:22, 214:8, 215:11, 218:24, 219:7, 219:10, 223:2, 223:25</p> <p>heroin-related [2] - 137:1, 173:8</p> <p>heroin/fentanyl [1] - 180:23</p> <p>HESTER [2] - 5:9, 234:21</p> <p>hidden [1] - 157:9</p> <p>High [1] - 229:7</p> <p>high [2] - 139:25, 237:8</p> <p>high-tech [1] - 237:8</p> <p>higher [1] - 186:20</p>
G				
<p>Gabapentin [3] - 208:3, 208:6, 208:9</p> <p>game [1] - 36:16</p> <p>Gary [3] - 74:8, 74:9, 75:1</p> <p>gateway [4] - 213:1, 213:6, 216:20, 216:21</p> <p>gears [1] - 109:7</p> <p>Gene [4] - 52:3, 52:4, 52:7, 52:8</p> <p>general [10] - 71:16, 103:18, 106:24, 137:21, 170:1, 175:9, 186:21, 209:20, 209:24, 219:4</p> <p>General [3] - 37:1, 37:12, 60:18</p> <p>generally [5] - 81:18, 106:6, 118:17, 120:22, 235:18</p>				
		H		
		<p>Haislip [5] - 52:3, 52:4, 52:5, 52:7, 52:8</p> <p>half [8] - 67:22, 103:12, 151:22, 174:16, 200:19, 202:2, 202:11, 202:20</p> <p>halfway [3] - 87:6, 88:5, 176:8</p> <p>hallmark [1] - 239:6</p> <p>hand [20] - 8:20,</p>		

<p>highest [4] - 110:23, 110:24, 220:18, 222:2</p> <p>Highlands [2] - 107:9, 107:18</p> <p>highlight [5] - 12:2, 17:2, 103:2, 217:7, 217:24</p> <p>highlighted [1] - 11:15</p> <p>highlighting [1] - 11:10</p> <p>highly [1] - 14:16</p> <p>Hilliard [1] - 66:6</p> <p>hire [1] - 10:21</p> <p>his/her [1] - 84:24</p> <p>historical [7] - 118:6, 125:11, 127:11, 129:9, 197:15, 209:25, 210:3</p> <p>history [9] - 54:21, 107:20, 151:19, 152:19, 152:20, 161:12, 180:12, 184:6, 186:8</p> <p>hold [2] - 101:3, 130:23</p> <p>holes [1] - 107:13</p> <p>honest [2] - 223:7, 224:5</p> <p>honing [1] - 131:1</p> <p>Honor [141] - 7:8, 7:13, 8:22, 14:1, 15:10, 19:4, 24:19, 36:15, 38:9, 45:13, 45:15, 45:22, 46:8, 46:17, 48:5, 48:13, 48:23, 50:25, 51:6, 51:20, 51:23, 53:10, 54:5, 55:14, 55:21, 56:19, 57:2, 57:6, 57:17, 57:21, 58:6, 59:12, 59:15, 59:18, 60:3, 60:4, 61:2, 61:4, 65:18, 65:19, 65:20, 66:21, 66:24, 67:14, 67:19, 67:24, 68:5, 68:13, 69:15, 70:7, 71:20, 74:15, 74:23, 75:4, 75:11, 77:8, 78:8, 78:10, 78:19, 79:22, 79:25, 80:9, 81:1, 82:18, 82:25, 85:9, 85:11, 95:22, 96:3, 96:14, 96:16, 96:19, 96:23, 96:24, 97:4, 102:6, 102:7, 102:14, 102:16, 112:23, 114:6, 114:15, 116:17, 119:18,</p>	<p>139:14, 140:3, 140:12, 143:3, 149:3, 149:4, 153:8, 154:9, 154:21, 167:11, 167:24, 168:13, 168:17, 168:22, 169:2, 169:15, 169:19, 170:11, 170:18, 171:2, 171:8, 171:12, 174:1, 174:2, 174:21, 175:13, 182:14, 191:2, 209:4, 209:6, 211:21, 212:3, 212:23, 214:12, 214:15, 215:18, 219:22, 224:9, 224:15, 224:23, 225:3, 225:4, 225:14, 225:21, 226:4, 226:7, 226:9, 226:19, 227:10, 228:13, 234:17, 234:20, 242:9, 242:13, 243:7, 243:15</p> <p>honor [1] - 57:12</p> <p>HONORABLE [1] - 1:17</p> <p>Honorable [1] - 7:1</p> <p>hope [4] - 13:12, 17:12, 34:7, 36:18</p> <p>hopefully [1] - 194:21</p> <p>Hopkins [2] - 101:10, 106:21</p> <p>hospital [1] - 111:17</p> <p>hospitals [1] - 22:15</p> <p>Hospitals [1] - 22:21</p> <p>hosted [1] - 32:13</p> <p>hot [1] - 217:14</p> <p>hour [2] - 67:22, 119:7</p> <p>house [1] - 122:18</p> <p>housekeeping [2] - 31:24, 171:17</p> <p>Houston [1] - 32:19</p> <p>HP [6] - 230:18, 230:19, 230:21, 231:1, 234:11, 234:15</p> <p>huge [2] - 62:7, 220:12</p> <p>Human [1] - 148:21</p> <p>hundred [2] - 139:24, 140:14</p> <p>hundreds [2] - 21:16, 21:17</p> <p>Huntington [14] - 3:10, 4:1, 23:3, 23:7, 87:12, 111:4,</p>	<p>113:25, 114:1, 114:2, 114:25, 141:12, 170:2, 174:14, 246:6</p> <p>HUNTINGTON [1] - 1:4</p> <p>Huntington-Cabell [2] - 87:12, 174:14</p> <p>hydrocodone [8] - 21:5, 64:13, 64:24, 65:13, 66:3, 66:8, 213:18, 218:20</p> <p style="text-align: center;">I</p> <p>IBM [1] - 230:16</p> <p>ICD-10 [1] - 101:1</p> <p>Idaho [1] - 234:2</p> <p>idea [5] - 95:8, 108:4, 110:8, 112:1, 155:25</p> <p>identical [1] - 32:1</p> <p>identification [1] - 47:15</p> <p>identified [21] - 21:6, 120:16, 125:12, 145:6, 146:23, 149:25, 158:18, 163:4, 164:10, 174:2, 176:13, 178:12, 178:14, 178:19, 180:16, 182:17, 186:3, 191:6, 192:3, 199:4, 203:11</p> <p>identifies [5] - 158:23, 192:2, 199:18, 200:12, 214:8</p> <p>identify [7] - 14:16, 47:22, 87:6, 112:2, 150:13, 160:4, 168:14</p> <p>identifying [2] - 174:3, 200:8</p> <p>identity [1] - 174:6</p> <p>II [1] - 151:18</p> <p>ii [1] - 30:14</p> <p>iii [1] - 30:15</p> <p>illegal [5] - 10:9, 12:6, 164:5, 216:24, 221:10</p> <p>illegitimately [1] - 94:12</p> <p>illicit [38] - 57:3, 134:20, 134:21, 138:7, 138:25, 141:8, 141:15, 146:25, 155:21, 158:14, 164:10, 164:13, 173:21, 176:25, 177:2,</p>	<p>177:24, 178:14, 178:15, 178:19, 178:24, 179:3, 179:11, 181:1, 182:1, 201:13, 201:18, 201:19, 202:15, 202:20, 203:1, 203:2, 203:11, 213:25, 214:7, 222:22, 223:2, 223:25</p> <p>illustrate [1] - 224:21</p> <p>illustrated [1] - 148:7</p> <p>illustration [1] - 215:2</p> <p>immediate [4] - 115:9, 158:23, 172:7, 173:1</p> <p>immediately [1] - 159:5</p> <p>impact [3] - 111:14, 220:8, 220:12</p> <p>impairs [1] - 110:2</p> <p>impeached [1] - 38:10</p> <p>impeaching [1] - 38:11</p> <p>impeachment [3] - 60:7, 60:9, 60:23</p> <p>implementation [1] - 212:13</p> <p>implicated [1] - 147:2</p> <p>importance [2] - 34:9, 34:23</p> <p>important [33] - 13:7, 13:9, 13:10, 73:7, 86:3, 86:6, 100:20, 115:7, 115:12, 116:19, 118:10, 118:11, 126:1, 127:19, 131:2, 136:10, 138:19, 141:13, 142:7, 142:20, 143:19, 147:3, 150:20, 152:17, 153:21, 172:20, 198:1, 220:9, 224:4, 239:6, 240:13, 243:3</p> <p>imported [2] - 141:3, 141:5</p> <p>impossible [4] - 135:1, 160:22, 238:20, 238:21</p> <p>imprimatur [1] - 114:17</p> <p>improvements [1] - 30:12</p> <p>IN [2] - 1:1, 1:18</p> <p>in-depth [2] - 150:22, 151:6</p> <p>inaccurate [1] - 61:18</p> <p>inappropriate [1] -</p>	<p>16:10</p> <p>incident [1] - 173:25</p> <p>include [6] - 113:25, 189:5, 190:17, 222:4, 225:1, 242:1</p> <p>included [9] - 118:14, 118:19, 142:10, 150:19, 188:14, 212:20, 222:24, 223:3</p> <p>includes [9] - 114:1, 116:11, 130:6, 130:7, 174:3, 189:23, 192:10, 200:8</p> <p>including [13] - 47:11, 47:21, 100:19, 100:24, 106:23, 111:3, 111:17, 112:9, 154:2, 162:3, 206:15, 223:1, 231:19</p> <p>Including [2] - 31:15, 31:16</p> <p>incomplete [1] - 86:12</p> <p>incorrectly [1] - 166:22</p> <p>increase [30] - 99:15, 100:3, 109:23, 117:12, 117:23, 124:6, 131:23, 136:1, 136:3, 139:2, 140:13, 140:15, 141:14, 144:12, 147:14, 147:23, 153:6, 153:23, 153:25, 195:5, 195:6, 198:3, 198:17, 198:18, 200:23, 204:11, 222:17, 222:21, 223:22</p> <p>increased [5] - 109:24, 130:9, 188:6, 211:15, 221:24</p> <p>increases [4] - 110:13, 130:17, 131:20, 139:23</p> <p>increasing [3] - 137:22, 198:2, 211:19</p> <p>Increasingly [1] - 188:3</p> <p>increasingly [1] - 233:17</p> <p>incredible [2] - 104:7, 109:6</p> <p>incredibly [1] - 189:5</p> <p>incumbent [1] - 31:13</p>
---	--	---	---	---

<p>independent [8] - 81:11, 81:12, 81:25, 82:6, 219:8, 225:11, 225:17, 225:24</p> <p>independently [2] - 210:20, 225:5</p> <p>independents [1] - 81:12</p> <p>indicate [2] - 116:5, 147:22</p> <p>indicated [2] - 44:23, 64:14</p> <p>indicates [2] - 200:22, 208:14</p> <p>indication [1] - 11:13</p> <p>indications [1] - 185:9</p> <p>indicative [1] - 64:22</p> <p>indicators [1] - 146:23</p> <p>individual [23] - 98:10, 106:10, 108:5, 126:15, 126:23, 133:6, 133:19, 162:23, 162:25, 163:1, 163:9, 163:13, 166:10, 167:20, 168:7, 168:15, 170:19, 174:14, 176:25, 193:17, 195:20, 210:24</p> <p>individual's [1] - 174:6</p> <p>individuals [1] - 49:5</p> <p>industries [5] - 230:14, 235:13, 235:20, 237:8, 237:20</p> <p>industry [17] - 32:12, 32:14, 32:21, 35:6, 35:9, 59:9, 230:16, 235:6, 235:9, 235:15, 235:24, 236:2, 237:7, 237:21, 239:11, 239:14, 240:6</p> <p>industry's [5] - 35:11, 75:19, 75:24, 76:10</p> <p>ineffective [1] - 42:15</p> <p>inexorably [1] - 197:9</p> <p>influence [2] - 240:9, 240:11</p> <p>influx [2] - 141:2, 141:5</p> <p>inform [3] - 16:14, 240:6, 240:7</p> <p>information [49] - 12:21, 15:8, 15:12, 15:13, 15:14, 15:25, 16:17, 25:25, 26:5, 26:24, 27:24, 35:11,</p>	<p>66:2, 79:3, 90:6, 90:12, 98:15, 109:25, 114:22, 116:16, 121:23, 122:4, 123:1, 131:8, 134:15, 149:20, 159:11, 159:24, 163:15, 164:17, 167:2, 167:21, 168:3, 168:7, 168:18, 168:20, 169:4, 169:5, 169:20, 170:20, 172:10, 174:3, 181:14, 187:11, 190:10, 206:2, 208:5, 221:1</p> <p>informed [3] - 12:4, 65:17, 243:25</p> <p>ingested [3] - 134:22, 166:10, 176:25</p> <p>initial [3] - 22:17, 82:2, 82:13</p> <p>initiate [1] - 31:13</p> <p>initiated [2] - 31:6, 216:10</p> <p>initiative [7] - 8:17, 50:4, 50:7, 50:10, 52:21, 54:15, 56:12</p> <p>injected [3] - 173:21, 176:20, 218:24</p> <p>injuries [7] - 100:7, 100:18, 107:3, 107:5, 110:9, 160:12</p> <p>injury [15] - 98:14, 100:4, 100:8, 100:9, 100:10, 106:22, 107:2, 112:9, 112:11, 121:7, 160:8, 160:11, 173:18</p> <p>Injury [4] - 101:14, 108:12, 108:21, 192:4</p> <p>injury-related [1] - 106:22</p> <p>Innovation [1] - 229:9</p> <p>innovation [2] - 230:5, 233:17</p> <p>Innovations [1] - 229:8</p> <p>inquiries [1] - 21:23</p> <p>inquiry [1] - 15:14</p> <p>inspection [1] - 30:4</p> <p>inspired [1] - 181:13</p> <p>instance [1] - 240:16</p> <p>instead [2] - 226:22, 239:1</p> <p>Institute [2] - 107:2, 110:20</p>	<p>instruction [1] - 101:7</p> <p>insufficient [1] - 205:3</p> <p>integrate [1] - 232:3</p> <p>Intelligence [1] - 104:14</p> <p>intend [1] - 244:24</p> <p>intended [5] - 42:7, 42:9, 78:18, 82:19, 143:8</p> <p>intent [1] - 29:19</p> <p>intention [1] - 46:3</p> <p>interchange [1] - 25:21</p> <p>interest [1] - 74:23</p> <p>interested [8] - 110:11, 110:25, 111:5, 111:6, 115:10, 129:15, 191:19, 204:17</p> <p>interesting [5] - 109:20, 126:3, 138:19, 181:5, 204:7</p> <p>interface [2] - 230:17, 232:25</p> <p>interference [1] - 93:22</p> <p>interject [1] - 140:2</p> <p>intermediaries [2] - 237:15, 239:10</p> <p>intermediary [4] - 237:19, 238:9, 238:23, 239:15</p> <p>internal [10] - 53:13, 69:4, 69:20, 69:24, 70:1, 70:18, 72:7, 241:23, 242:17, 242:21</p> <p>internally [2] - 123:25, 243:5</p> <p>international [3] - 100:15, 103:23, 228:23</p> <p>International [2] - 100:17, 108:12</p> <p>internationally [1] - 113:15</p> <p>internet [26] - 9:20, 9:23, 10:8, 10:12, 10:15, 10:16, 10:18, 10:19, 10:20, 10:24, 11:1, 11:9, 11:11, 11:15, 12:11, 12:15, 17:6, 21:18, 23:11, 23:15, 49:24, 62:5, 221:12, 232:8</p> <p>Internet [1] - 9:21</p> <p>Interorganizational [1] - 232:25</p> <p>interpret [3] - 42:25, 80:1, 198:24</p>	<p>interpreted [1] - 185:24</p> <p>interrelated [1] - 68:21</p> <p>interrupt [3] - 31:20, 32:2, 66:19</p> <p>interrupted [1] - 14:2</p> <p>intervention [3] - 106:9, 111:22, 150:14</p> <p>interviews [1] - 76:13</p> <p>intoxication [3] - 170:3, 172:14, 173:2</p> <p>introduce [4] - 74:24, 97:21, 170:10, 227:24</p> <p>introduced [3] - 59:25, 163:23, 212:4</p> <p>introducing [1] - 170:13</p> <p>introduction [1] - 216:14</p> <p>inverse [2] - 211:18, 213:22</p> <p>investigate [5] - 20:10, 84:20, 92:20, 93:1, 93:7</p> <p>investigation [7] - 63:1, 94:3, 122:25, 174:24, 176:1, 176:13, 179:8</p> <p>investigations [10] - 20:21, 20:23, 21:5, 21:16, 30:23, 34:17, 34:24, 61:24, 62:1, 62:3</p> <p>investigative [1] - 15:13</p> <p>investigator [1] - 7:19</p> <p>Investigator [1] - 49:15</p> <p>investigators [1] - 7:23</p> <p>invoked [1] - 60:15</p> <p>involve [4] - 82:9, 105:25, 154:18, 190:2</p> <p>involved [28] - 23:15, 71:6, 106:1, 106:13, 110:1, 110:17, 152:20, 154:16, 155:16, 156:6, 158:18, 160:14, 160:16, 161:24, 162:17, 162:24, 162:25, 163:13, 164:8, 165:10, 172:24, 181:23, 185:3, 188:5, 189:25, 220:22, 224:6</p>	<p>involvement [7] - 107:20, 109:21, 110:9, 110:12, 113:23, 137:22, 154:18</p> <p>involves [2] - 82:7, 160:23</p> <p>involving [2] - 138:22, 222:22</p> <p>Irpino [4] - 3:7, 57:4, 57:17, 57:18</p> <p>IRPINO [6] - 34:16, 34:19, 57:9, 57:12, 57:17, 57:21</p> <p>irregardless [1] - 172:24</p> <p>ISIA [1] - 5:4</p> <p>ISO [4] - 22:23, 23:10, 23:21, 23:22</p> <p>issue [6] - 16:5, 34:1, 56:6, 61:15, 90:11, 116:7</p> <p>issued [4] - 17:17, 22:7, 23:22, 167:17</p> <p>issues [5] - 15:1, 30:16, 46:1, 192:14, 213:6</p> <p>italicized [1] - 84:8</p> <p>Item [1] - 86:7</p> <p>itself [6] - 76:2, 79:14, 79:20, 80:4, 189:16, 225:10</p> <p>IV [1] - 151:18</p>
J				
<p>Jackson [1] - 6:8</p> <p>Jakki [3] - 227:11, 227:15, 227:25</p> <p>JAKKI [1] - 227:18</p> <p>Jalal [5] - 195:11, 196:17, 196:21, 196:24, 209:17</p> <p>JAMA [3] - 142:14, 143:9, 148:15</p> <p>January [6] - 47:20, 64:11, 64:20, 65:11, 87:23, 88:4</p> <p>JASIEWICZ [1] - 5:4</p> <p>JEFFREY [1] - 5:13</p> <p>JENNIFER [1] - 4:12</p> <p>Jersey [1] - 180:20</p> <p>job [2] - 164:25, 234:15</p> <p>Joe [1] - 90:8</p> <p>John [1] - 98:22</p> <p>Johns [2] - 101:10, 106:21</p> <p>join [1] - 80:21</p> <p>joined [1] - 104:13</p>				

<p>joint [3] - 31:5, 31:11, 35:13</p> <p>joke [2] - 88:8, 112:18</p> <p>Jordan [1] - 52:13</p> <p>JOSEPH [1] - 6:4</p> <p>Journal [5] - 144:4, 191:10, 231:15, 232:1, 236:8</p> <p>journal [1] - 242:4</p> <p>journals [3] - 148:15, 233:12, 233:13</p> <p>JR [2] - 2:3, 2:15</p> <p>Juan [2] - 2:5, 2:17</p> <p>Judge [10] - 7:2, 63:14, 109:1, 168:6, 175:6, 182:6, 205:14, 209:21, 214:19, 244:2</p> <p>judge [4] - 109:4, 155:4, 174:13, 179:21</p> <p>JUDGE [1] - 1:17</p> <p>judgment [1] - 93:24</p> <p>Judith [1] - 109:11</p> <p>July [1] - 91:8</p> <p>jump [1] - 22:5</p> <p>June [5] - 7:4, 24:6, 26:22, 246:9, 246:15</p> <p>JUNE [1] - 1:19</p> <p>junior [1] - 229:5</p> <p>junior-level [1] - 229:5</p> <p>justice [1] - 119:4</p> <p>Justice [2] - 15:24, 16:24</p>	<p>138:2, 139:14, 139:16, 140:12, 140:16, 140:18, 141:17, 141:19, 143:3, 143:5, 144:6, 144:8, 144:22, 144:24, 147:7, 147:9, 149:1, 149:5, 151:1, 151:3, 152:3, 152:5, 153:12, 153:13, 154:9, 154:11, 154:21, 168:2, 168:16, 169:1, 169:8, 209:8, 219:22, 219:24, 220:23, 220:25, 222:9, 224:9, 224:23, 225:11, 226:4, 226:7</p> <p>Kearse [12] - 102:13, 153:11, 155:13, 158:10, 158:22, 168:25, 182:21, 186:1, 209:7, 222:14, 224:21, 225:8</p> <p>keen [1] - 145:11</p> <p>keep [4] - 39:3, 67:4, 91:13, 113:5</p> <p>keeping [1] - 111:9</p> <p>Kelly [1] - 6:8</p> <p>kept [2] - 123:24, 216:15</p> <p>Kessler [1] - 4:17</p> <p>key [10] - 113:22, 125:14, 126:20, 128:4, 144:19, 150:18, 151:9, 152:11, 198:5, 216:12</p> <p>kill [1] - 189:16</p> <p>kind [6] - 67:9, 99:18, 108:7, 149:12, 210:9, 239:7</p> <p>kinds [1] - 153:2</p> <p>knowing [3] - 34:9, 34:23, 169:25</p> <p>knowledge [23] - 14:23, 14:24, 17:10, 22:25, 23:4, 23:8, 23:25, 24:3, 24:4, 24:13, 26:21, 29:20, 29:24, 30:19, 35:21, 55:25, 56:8, 69:13, 162:16, 164:7, 190:21, 203:3, 219:8</p> <p>known [4] - 192:15, 207:15, 207:17, 231:13</p> <p>knows [5] - 51:4,</p>	<p>54:20, 55:7, 68:21, 73:10</p> <p>KOUBA [1] - 3:14</p> <p>Kun [1] - 192:3</p> <p>Kyle [2] - 9:16, 49:9</p>	<p>L</p> <p>LA [1] - 3:8</p> <p>laboratories [1] - 180:17</p> <p>lag [2] - 25:8, 28:13</p> <p>laid [2] - 225:12, 225:16</p> <p>landmark [1] - 142:21</p> <p>language [15] - 38:10, 40:17, 80:1, 84:9, 86:13, 87:1, 87:9, 87:14, 88:6, 92:15, 93:16, 94:15, 95:1, 178:18, 240:4</p> <p>Lanier [1] - 3:4</p> <p>large [14] - 62:3, 62:5, 64:12, 64:18, 85:2, 86:11, 134:9, 139:2, 140:14, 141:2, 192:1, 231:3, 234:11</p> <p>largely [3] - 129:20, 137:23, 201:1</p> <p>larger [3] - 33:22, 128:13, 197:5</p> <p>largest [2] - 118:20, 144:12</p> <p>laser [1] - 234:12</p> <p>last [26] - 8:10, 10:3, 14:10, 17:1, 18:7, 18:23, 26:9, 40:13, 40:19, 41:8, 49:1, 72:16, 74:16, 84:15, 92:12, 94:14, 151:1, 174:22, 184:3, 201:6, 204:11, 207:7, 215:14, 223:6, 242:24</p> <p>Last [3] - 30:8, 218:9, 218:21</p> <p>late [2] - 62:12, 244:25</p> <p>latest [1] - 87:21</p> <p>Latin [1] - 219:1</p> <p>launching [2] - 50:9, 52:21</p> <p>Laura [1] - 155:8</p> <p>LAURA [1] - 5:10</p> <p>Law [3] - 3:4, 3:7, 3:12</p> <p>law [9] - 15:13, 38:22, 81:10, 81:16, 177:14, 179:7, 180:16, 180:19, 181:25</p> <p>lawfully [1] - 187:3</p>	<p>laws [2] - 82:16, 212:13</p> <p>lawsuit [2] - 37:3</p> <p>lawyer [1] - 86:23</p> <p>lay [4] - 45:25, 55:24, 69:11, 102:10</p> <p>lead [4] - 13:2, 109:14, 153:11, 219:16</p> <p>leadership [1] - 77:6</p> <p>leading [7] - 65:15, 65:21, 65:22, 65:23, 68:23, 148:15, 153:10</p> <p>learn [5] - 21:22, 56:12, 63:4, 69:25, 235:23</p> <p>learned [6] - 20:6, 36:15, 56:21, 56:24, 108:3, 111:23</p> <p>learning [1] - 7:17</p> <p>least [12] - 27:7, 28:17, 68:18, 134:11, 135:17, 194:3, 197:10, 197:15, 202:11, 202:20, 210:3, 227:8</p> <p>leave [2] - 123:19, 226:23</p> <p>led [2] - 214:3, 214:4</p> <p>Lee [1] - 3:12</p> <p>left [19] - 27:8, 38:24, 45:1, 46:1, 74:10, 86:24, 129:6, 176:2, 176:4, 180:10, 180:11, 180:15, 195:18, 196:25, 208:20, 210:9, 215:17, 238:6, 238:10</p> <p>left-hand [7] - 129:6, 180:10, 180:15, 195:18, 196:25, 210:9, 238:6</p> <p>legal [9] - 41:15, 41:16, 43:25, 84:19, 92:19, 92:25, 93:7, 95:12, 181:20</p> <p>legitimate [1] - 94:9</p> <p>legitimately [1] - 163:20</p> <p>length [2] - 46:19, 49:1</p> <p>lengthy [1] - 82:19</p> <p>Leon [2] - 2:4, 2:16</p> <p>less [13] - 30:10, 118:15, 126:25, 128:25, 157:25, 181:8, 181:10, 181:18, 183:14, 194:6, 195:8,</p>	<p>198:10, 220:4</p> <p>lethal [1] - 180:23</p> <p>letter [16] - 17:1, 43:13, 52:25, 53:3, 53:6, 53:11, 53:12, 53:23, 54:2, 54:3, 54:6, 56:1, 56:2, 60:17, 73:6, 94:24</p> <p>letters [18] - 41:24, 42:6, 42:8, 42:10, 42:14, 42:18, 42:20, 42:24, 43:22, 46:5, 46:19, 47:8, 47:14, 47:25, 48:18, 48:19, 62:15, 73:5</p> <p>letters [1] - 47:11</p> <p>level [11] - 113:24, 116:2, 126:5, 189:4, 189:14, 198:17, 205:1, 229:5, 229:6</p> <p>levels [2] - 94:5, 110:10</p> <p>Levin [1] - 2:12</p> <p>LEYIMU [1] - 4:8</p> <p>liability [1] - 25:1</p> <p>liaison [2] - 8:11, 30:22</p> <p>Liberty [2] - 106:16, 107:1</p> <p>license [4] - 29:17, 29:21, 39:17, 91:21</p> <p>licensed [3] - 10:13, 10:14, 11:2</p> <p>licensure [1] - 82:14</p> <p>licit [2] - 140:24</p> <p>life [2] - 150:23, 162:9</p> <p>lifeline [1] - 57:4</p> <p>Lifetime [1] - 232:24</p> <p>likelihood [1] - 94:2</p> <p>likewise [1] - 164:2</p> <p>limited [2] - 59:25, 189:20</p> <p>limits [1] - 80:5</p> <p>LINDA [1] - 4:5</p> <p>Linden [1] - 66:13</p> <p>line [11] - 15:14, 16:20, 16:23, 17:20, 35:23, 44:20, 87:6, 136:4, 136:12, 204:18, 217:9</p> <p>Line [4] - 37:22, 46:12, 91:10, 150:11</p> <p>lines [2] - 78:5, 87:5</p> <p>link [1] - 149:15</p> <p>linked [1] - 149:16</p> <p>linking [1] - 149:19</p> <p>Lisa [2] - 6:18, 246:3</p> <p>list [6] - 18:9, 160:7, 190:8, 190:10, 232:13, 242:12</p>
<p>K</p> <p>Kaiser [1] - 236:10</p> <p>KEARSE [89] - 4:2, 96:24, 97:1, 97:4, 97:17, 97:20, 99:3, 99:20, 102:6, 102:14, 102:20, 102:22, 105:4, 105:8, 105:16, 105:21, 112:22, 112:25, 114:6, 114:15, 114:19, 115:19, 115:22, 118:24, 119:1, 119:18, 119:19, 121:2, 122:6, 122:8, 126:10, 126:12, 128:6, 128:7, 129:2, 129:4, 131:11, 131:13, 135:7, 135:9, 135:23, 135:24, 136:17, 136:20, 137:15, 137:17, 137:25,</p>					

<p>listed [6] - 70:12, 161:6, 164:18, 177:6, 218:13, 238:10</p> <p>lists [1] - 11:5</p> <p>literal [1] - 75:12</p> <p>literally [2] - 56:17, 68:15</p> <p>literature [8] - 113:1, 113:4, 141:25, 142:1, 153:17, 166:6, 212:20, 213:20</p> <p>litigation [2] - 78:14, 236:17</p> <p>live [3] - 99:14, 238:18, 238:20</p> <p>LLC [1] - 2:4</p> <p>local [5] - 91:23, 107:25, 122:23, 122:24, 230:25</p> <p>locate [2] - 67:10, 112:4</p> <p>located [1] - 180:17</p> <p>Logan [2] - 6:5, 6:12</p> <p>London [3] - 98:22, 98:23, 99:5</p> <p>long-term [1] - 131:16</p> <p>longer-term [1] - 197:5</p> <p>look [85] - 14:10, 16:8, 16:25, 17:25, 18:6, 18:7, 19:17, 21:5, 24:17, 25:14, 25:16, 29:6, 40:20, 47:4, 49:17, 66:7, 76:21, 81:22, 83:22, 84:15, 98:9, 98:14, 99:15, 110:8, 115:1, 115:25, 116:5, 116:24, 117:5, 118:17, 119:9, 124:4, 126:3, 126:9, 127:8, 137:2, 139:11, 139:13, 140:9, 141:13, 142:21, 151:17, 153:25, 154:4, 154:6, 158:12, 163:2, 167:9, 172:4, 173:15, 175:18, 177:11, 178:8, 178:11, 178:15, 179:4, 179:7, 179:19, 187:12, 192:13, 194:10, 194:12, 194:14, 195:5, 197:23, 200:1, 204:4, 204:23, 205:15,</p>	<p>210:18, 212:7, 215:10, 215:23, 216:11, 218:16, 218:22, 222:7, 223:13, 223:14, 237:12, 238:14, 242:3, 244:1, 244:12</p> <p>looked [23] - 14:25, 86:16, 117:24, 117:25, 118:19, 124:15, 138:20, 143:24, 151:5, 158:9, 172:20, 172:25, 175:22, 178:23, 181:4, 181:6, 186:17, 191:17, 192:13, 206:22, 207:11, 208:7, 221:18</p> <p>looking [42] - 17:23, 21:10, 21:17, 49:4, 83:6, 100:1, 100:2, 106:2, 107:14, 109:5, 111:6, 113:4, 113:22, 116:25, 122:5, 123:7, 129:20, 132:11, 134:9, 134:17, 134:19, 137:2, 144:20, 145:16, 149:19, 153:17, 155:24, 168:2, 176:12, 176:13, 187:23, 193:7, 195:12, 198:23, 198:24, 203:13, 204:13, 210:17, 216:21, 221:17, 231:17</p> <p>looks [14] - 19:19, 58:21, 86:12, 111:10, 122:20, 134:2, 142:1, 169:3, 169:9, 189:3, 210:12, 210:20, 222:2</p> <p>losing [1] - 31:18</p> <p>loud [6] - 17:3, 29:5, 30:9, 34:6, 38:1, 47:5</p> <p>loudly [1] - 34:7</p> <p>Louis [1] - 232:15</p> <p>love [3] - 234:10, 235:25, 236:11</p> <p>lovely [1] - 236:5</p> <p>low [7] - 131:17, 131:25, 156:16, 189:5, 195:1, 195:4, 197:25</p> <p>lower [2] - 157:6,</p>	<p>186:21</p> <p>lowest [1] - 223:19</p> <p>luck [1] - 96:6</p>	<p>M</p> <p>M.B [1] - 103:20</p> <p>ma'am [1] - 76:4</p> <p>mad [1] - 121:4</p> <p>Madison [1] - 229:16</p> <p>Magazine [1] - 3:7</p> <p>magazines [1] - 242:3</p> <p>Magazines [1] - 242:3</p> <p>magnitude [1] - 202:14</p> <p>MAHADY [1] - 6:4</p> <p>Mahoney [1] - 64:2</p> <p>mail [4] - 49:5, 49:8, 49:10, 49:12</p> <p>main [4] - 118:2, 124:25, 219:15</p> <p>MAINIGI [1] - 4:12</p> <p>maintaining [1] - 44:7</p> <p>MAJESTRO [1] - 2:6</p> <p>Majestro [1] - 2:6</p> <p>major [4] - 81:18, 127:9, 153:5, 220:6</p> <p>majority [2] - 185:7, 185:10</p> <p>male [1] - 215:5</p> <p>males [3] - 151:23, 152:12, 161:11</p> <p>man [1] - 218:11</p> <p>man's [1] - 175:8</p> <p>Management [1] - 232:1</p> <p>management [2] - 106:2, 233:14</p> <p>manager [1] - 88:6</p> <p>mandatory [1] - 212:13</p> <p>manifestation [1] - 210:5</p> <p>manner [5] - 39:2, 81:9, 163:14, 172:17, 174:22</p> <p>Manual [1] - 49:15</p> <p>manufacture [1] - 47:10</p> <p>manufactured [1] - 138:25</p> <p>manufacturer [3] - 229:25, 238:10, 238:12</p> <p>manufacturer's [1] - 238:19</p> <p>manufacturers [4] - 230:11, 232:2, 233:15, 241:19</p> <p>map [1] - 99:6</p>	<p>Mapes [16] - 9:5, 9:15, 10:5, 10:6, 11:8, 13:21, 14:13, 15:4, 16:15, 16:18, 17:7, 20:9, 33:24, 35:14, 35:17, 79:11</p> <p>Mapes' [1] - 18:4</p> <p>March [3] - 58:25, 59:13, 171:20</p> <p>margins [1] - 237:15</p> <p>mark [2] - 93:17, 93:18</p> <p>MARK [1] - 3:16</p> <p>marked [2] - 179:24, 228:14</p> <p>market [4] - 238:7, 238:9, 239:6, 241:18</p> <p>Marketing [8] - 227:25, 228:4, 229:6, 229:7, 231:15, 232:18, 232:23, 240:15</p> <p>marketing [37] - 230:5, 231:7, 232:16, 233:10, 233:15, 233:19, 233:22, 233:23, 234:4, 234:18, 234:24, 236:2, 236:21, 237:2, 237:25, 238:14, 239:19, 239:21, 239:24, 239:25, 240:4, 240:9, 240:11, 240:13, 240:18, 240:21, 241:7, 241:11, 241:17, 241:18, 241:21, 242:3, 242:16, 242:25, 243:2</p> <p>marketplace [1] - 243:6</p> <p>markets [1] - 231:5</p> <p>Marshall [1] - 111:4</p> <p>Maryland [3] - 101:9, 108:17, 110:4</p> <p>Master's [5] - 105:12, 233:22, 234:8, 234:9, 234:16</p> <p>Masters [8] - 41:18, 43:21, 44:6, 44:12, 94:14, 104:5, 105:18</p> <p>matched [1] - 145:20</p> <p>material [1] - 242:22</p> <p>materials [4] - 66:16, 174:19, 177:14, 241:17</p> <p>math [2] - 202:7, 202:14</p> <p>mathematical [1] -</p>	<p>195:23</p> <p>matter [10] - 11:14, 27:4, 31:24, 57:23, 63:20, 114:3, 133:23, 155:17, 216:19, 246:5</p> <p>matters [1] - 155:12</p> <p>Mays [13] - 9:14, 10:6, 11:4, 11:5, 11:9, 12:4, 12:8, 12:14, 12:21, 13:14, 15:4, 20:9</p> <p>MC [3] - 191:1, 191:7, 195:15</p> <p>MC-West [3] - 191:1, 191:7, 195:15</p> <p>MC-WV-1229 [1] - 209:17</p> <p>McCann [4] - 243:23, 244:4, 244:6, 244:14</p> <p>MCCLURE [2] - 6:3, 234:20</p> <p>McDowell [1] - 111:24</p> <p>MCGINNESS [1] - 4:2</p> <p>McKesson [42] - 5:8, 45:2, 45:10, 47:1, 47:11, 47:19, 47:24, 48:17, 63:20, 63:22, 64:2, 64:11, 64:16, 64:18, 64:20, 65:2, 65:11, 65:17, 66:2, 66:6, 66:12, 66:16, 68:9, 69:4, 69:19, 69:25, 70:18, 71:3, 71:10, 72:2, 72:7, 72:8, 74:12, 78:6, 78:7, 86:8, 86:10, 155:8, 162:21, 203:1</p> <p>McKesson's [11] - 36:23, 37:9, 40:8, 44:18, 44:19, 44:24, 64:1, 64:12, 64:17, 66:7, 86:9</p> <p>MDL [2] - 45:18, 46:12</p> <p>mean [12] - 13:4, 20:19, 21:11, 82:1, 148:10, 155:19, 189:8, 202:24, 241:15, 241:16, 244:14, 244:15</p> <p>meaning [7] - 80:5, 150:23, 183:11, 184:16, 219:4, 238:7</p> <p>means [6] - 28:7, 82:2, 136:9, 164:5, 219:2, 230:25</p> <p>meant [2] - 18:17, 218:22</p> <p>mechanical [1] - 6:19</p> <p>mechanisms [1] -</p>
---	---	---	--	---	---

<p>231:18 media [2] - 76:13, 76:14 Medicaid [1] - 111:17 Medical [27] - 110:5, 111:8, 113:15, 121:21, 122:23, 123:6, 134:13, 137:6, 143:17, 144:4, 150:1, 150:21, 151:6, 159:11, 159:14, 159:25, 160:4, 160:14, 160:17, 161:9, 161:15, 166:25, 167:18, 169:20, 170:20, 176:23, 236:9 medical [18] - 88:13, 88:17, 93:24, 103:9, 103:17, 103:21, 103:22, 103:23, 103:25, 113:1, 122:21, 122:24, 146:24, 148:15, 185:8, 189:3, 189:11, 218:25 medically [1] - 94:5 medication [5] - 187:4, 188:19, 188:25, 190:7, 190:14 medications [1] - 236:22 Medicine [2] - 101:5, 101:9 medicine [3] - 103:19, 104:21, 107:12 meet [3] - 30:10, 30:20, 109:11 meeting [37] - 8:18, 9:12, 9:14, 9:19, 9:21, 9:23, 9:24, 10:1, 10:5, 10:6, 13:7, 16:16, 16:19, 17:2, 17:3, 17:11, 17:13, 17:15, 17:21, 18:21, 20:8, 21:7, 31:6, 51:2, 64:20, 65:10, 70:19, 71:2, 71:5, 71:8, 71:9, 71:13, 71:16, 71:17, 72:2, 72:6, 82:20 meetings [9] - 30:21, 30:23, 31:1, 31:8, 31:14, 71:4, 71:6, 72:5, 72:7 member [3] - 108:9, 108:11, 238:8 memo [10] - 14:8,</p>	<p>15:21, 16:10, 18:4, 53:13, 54:6, 54:7, 54:10, 54:11 Memorandum [1] - 47:1 memory [1] - 179:18 memos [2] - 16:12, 16:13 men [2] - 146:7, 146:21 mentioned [9] - 8:13, 83:10, 106:15, 135:10, 139:7, 144:25, 204:17, 218:10, 232:15 Mercer [1] - 111:23 merely [1] - 42:25 messed [1] - 244:23 met [3] - 64:11, 100:16, 155:9 metabolized [4] - 137:5, 166:11, 188:23, 219:12 metabolizes [1] - 165:21 meth [2] - 200:19, 201:1 methadone [1] - 215:12 methamphetamine [6] - 200:10, 200:13, 200:23, 201:20, 203:4, 206:16 method [1] - 88:16 methodologies [1] - 244:10 methodology [6] - 118:21, 118:23, 119:21, 119:25, 121:21, 148:8 methods [8] - 120:2, 120:8, 120:17, 120:18, 120:22, 121:6, 149:21, 221:9 Mexico [2] - 60:20, 88:15 mic [2] - 120:3, 122:14 MICHAEL [2] - 2:15, 3:9 Michael [1] - 9:15 microphone [1] - 228:5 microphones [2] - 67:1 mid [1] - 197:11 middle [6] - 84:16, 88:4, 94:16, 192:23, 197:4, 210:2 middleman [1] - 237:14</p>	<p>Midwest [1] - 180:19 might [20] - 16:4, 21:16, 31:2, 39:23, 100:3, 103:12, 104:23, 110:1, 118:25, 133:22, 160:9, 169:15, 177:15, 183:19, 190:18, 192:15, 242:3, 243:19 MILDRED [1] - 3:3 mind [7] - 57:24, 77:10, 77:18, 78:12, 88:4, 205:17, 242:4 minimum [2] - 67:5, 71:13 minor [2] - 30:6, 197:12 minute [7] - 17:25, 31:20, 36:1, 65:21, 140:1, 212:22, 214:13 minutes [8] - 85:22, 119:2, 182:8, 226:15, 226:20, 226:24, 227:8, 235:2 miscounted [1] - 167:5 mispronounce [1] - 208:21 missed [1] - 160:9 missing [1] - 91:16 mistake [5] - 15:23, 16:18, 16:21, 16:22, 57:11 mistaken [2] - 18:14, 89:1 mistakenly [1] - 94:3 Mitchell [1] - 2:12 mixed [1] - 154:7 mixture [1] - 180:24 model [1] - 231:15 moderate [1] - 184:8 modification [2] - 22:14, 22:18 modified [1] - 17:22 MOHR [1] - 227:18 Mohr [24] - 226:21, 227:11, 227:12, 227:15, 227:22, 227:25, 228:1, 228:7, 228:16, 229:11, 231:6, 232:10, 233:9, 233:18, 234:17, 234:23, 235:5, 236:13, 236:19, 237:3, 239:9, 242:15, 243:9, 243:17</p>	<p>molecule [5] - 134:20, 134:21, 134:22, 219:17, 219:18 molecules [5] - 155:24, 156:1, 164:8, 185:6, 203:13 moment [4] - 49:17, 61:2, 66:20, 122:3 money [1] - 108:24 Monitoring [9] - 62:14, 62:20, 63:6, 65:12, 73:18, 143:21, 150:3, 151:13, 151:15 monitoring [6] - 65:13, 66:3, 66:17, 68:10, 69:5, 145:22 Montana [3] - 228:2, 228:3, 229:4 month [3] - 25:10, 28:10, 32:17 months [1] - 22:12 Morgantown [1] - 97:25 morning [21] - 7:10, 7:12, 7:13, 7:14, 7:15, 36:21, 36:22, 50:6, 62:12, 67:25, 79:9, 96:24, 96:25, 97:15, 97:16, 97:17, 97:21, 243:10, 244:21, 244:25, 245:5 morphine [19] - 136:21, 136:25, 137:3, 137:5, 137:7, 137:9, 165:21, 166:10, 166:18, 166:22, 167:6, 170:3, 172:14, 173:2, 177:6, 218:14, 218:18, 219:13, 219:15 morphine-related [2] - 166:18, 167:6 Morris [1] - 6:15 mortality [16] - 100:9, 100:10, 121:7, 122:1, 131:16, 141:12, 142:10, 144:13, 147:15, 147:16, 147:23, 192:24, 194:2, 195:22, 197:13, 220:19 Mortality [1] - 195:19 mortar [6] - 10:14, 10:21, 10:23, 10:25, 12:16, 12:22 most [30] - 88:16,</p>	<p>90:14, 91:22, 104:23, 108:1, 112:12, 115:7, 115:11, 117:8, 127:22, 131:2, 132:15, 133:19, 136:10, 138:19, 141:13, 142:7, 142:11, 142:20, 147:14, 154:1, 181:19, 192:13, 198:1, 201:18, 216:9, 231:13, 233:16, 237:11, 240:13 Most [1] - 242:18 mostly [5] - 35:13, 81:11, 129:19, 131:25, 194:25 motion [2] - 243:21, 244:17 Motley [5] - 2:9, 3:14, 4:3, 4:5, 4:8 motor [1] - 109:22 MOUGEY [1] - 2:12 Mountain [1] - 223:10 move [14] - 51:21, 57:20, 59:12, 60:7, 61:4, 72:10, 119:21, 144:7, 158:6, 167:24, 169:12, 194:21, 224:15, 228:5 moved [1] - 71:15 movements [1] - 67:5 movies [1] - 104:17 moving [2] - 39:6, 241:5 MR [161] - 2:3, 2:6, 2:9, 2:12, 2:15, 3:9, 3:11, 3:16, 4:17, 5:9, 5:10, 5:13, 6:4, 7:8, 7:11, 7:13, 7:16, 8:19, 8:25, 13:18, 13:19, 14:1, 14:4, 15:10, 15:17, 15:18, 17:24, 18:2, 18:23, 19:7, 19:25, 20:4, 24:19, 24:21, 24:23, 31:20, 31:21, 31:22, 32:4, 32:6, 32:8, 33:18, 33:19, 34:16, 34:18, 34:19, 34:20, 34:21, 36:1, 36:6, 36:9, 37:2, 37:21, 38:9, 38:16, 43:24, 45:4, 45:15, 46:8, 48:5, 50:25, 51:16, 53:10, 54:5, 54:16, 55:6, 55:14, 55:20,</p>
--	---	--	--	---

56:17, 57:6, 57:9, 57:11, 57:12, 57:17, 57:21, 59:15, 60:4, 63:10, 65:15, 65:18, 66:19, 66:23, 67:7, 67:13, 68:13, 68:18, 69:8, 70:17, 71:12, 71:20, 74:5, 74:23, 75:11, 75:21, 77:15, 79:22, 80:9, 83:9, 83:13, 83:18, 85:11, 85:14, 85:18, 85:20, 91:14, 91:18, 94:19, 94:21, 95:19, 95:24, 96:4, 96:10, 96:14, 96:16, 96:19, 96:23, 119:12, 169:24, 170:12, 174:12, 175:5, 205:14, 205:20, 209:4, 209:11, 209:21, 209:23, 210:25, 211:2, 212:3, 212:6, 212:23, 213:16, 214:12, 214:15, 214:18, 214:21, 214:22, 215:22, 219:20, 226:9, 226:17, 227:4, 227:10, 227:21, 228:13, 228:15, 234:17, 234:21, 235:1, 242:8, 242:12, 242:14, 243:7, 243:15, 243:19, 244:2, 244:5, 244:14, 244:19, 245:4 MS [243] - 3:3, 3:6, 3:14, 4:2, 4:5, 4:8, 4:12, 4:12, 4:15, 5:3, 5:4, 5:10, 6:3, 6:7, 6:14, 36:15, 36:20, 37:7, 37:20, 37:22, 37:25, 38:13, 38:19, 44:9, 45:11, 45:21, 46:17, 46:23, 48:11, 48:13, 48:16, 48:24, 51:6, 51:7, 51:20, 51:24, 53:17, 53:20, 53:21, 54:9, 54:23, 54:25, 55:13, 56:9, 56:19, 57:2, 57:16, 58:5, 58:8, 59:12, 59:18, 61:2, 61:4, 61:5, 63:17, 65:24, 65:25, 66:22, 67:17, 67:24, 68:4, 68:6, 68:17, 68:25, 69:2, 69:15, 69:17, 70:6, 70:8, 70:23, 71:23,	71:24, 74:7, 74:14, 74:17, 75:4, 75:16, 75:17, 76:6, 76:7, 77:8, 78:10, 78:18, 78:21, 78:22, 79:25, 80:16, 80:25, 81:2, 82:18, 82:25, 83:4, 83:11, 83:15, 83:20, 83:21, 83:25, 84:2, 85:9, 95:21, 96:2, 96:11, 96:24, 97:1, 97:4, 97:17, 97:20, 99:3, 99:20, 102:6, 102:7, 102:14, 102:20, 102:22, 105:4, 105:8, 105:16, 105:21, 112:22, 112:25, 114:6, 114:15, 114:19, 115:19, 115:22, 118:24, 119:1, 119:18, 119:19, 121:2, 122:6, 122:8, 126:10, 126:12, 128:6, 128:7, 129:2, 129:4, 131:11, 131:13, 135:7, 135:9, 135:23, 135:24, 136:17, 136:20, 137:15, 137:17, 137:25, 138:2, 139:14, 139:16, 140:3, 140:12, 140:16, 140:18, 141:17, 141:19, 143:3, 143:5, 144:6, 144:8, 144:22, 144:24, 147:7, 147:9, 149:1, 149:5, 151:1, 151:3, 152:3, 152:5, 153:8, 153:10, 153:12, 153:13, 154:9, 154:11, 154:21, 154:24, 155:1, 155:4, 155:7, 161:19, 167:9, 167:13, 167:24, 168:2, 168:5, 168:13, 168:16, 168:22, 169:1, 169:6, 169:8, 169:11, 169:19, 170:11, 170:18, 171:2, 171:5, 171:8, 171:12, 171:13, 174:1, 174:8, 174:21, 175:4, 175:13, 175:14, 179:21, 179:23,	182:6, 182:14, 182:15, 191:1, 191:3, 194:18, 194:20, 199:6, 199:9, 209:6, 209:8, 211:21, 211:23, 215:18, 219:22, 219:24, 220:23, 220:25, 222:9, 222:11, 222:13, 224:9, 224:17, 224:23, 225:4, 225:11, 225:21, 226:4, 226:7, 234:20, 234:22 Mt [3] - 3:15, 4:4, 4:9 multiple [15] - 23:12, 23:13, 23:17, 57:7, 110:17, 133:20, 146:13, 147:2, 154:1, 160:16, 160:24, 161:25, 188:3, 188:15, 235:12 must [3] - 94:4, 95:10, 184:16 Mutual [2] - 106:16, 107:1 mutually [1] - 25:21 myth [2] - 237:13, 237:18	218:1, 218:7, 231:1, 241:8 National [5] - 110:20, 117:16, 118:3, 123:16, 124:12 nationally [2] - 197:22, 198:10 nature [3] - 168:10, 171:9, 242:5 nearly [3] - 67:25, 151:22, 200:19 necessarily [6] - 10:19, 20:23, 28:2, 71:18, 170:6, 192:11 need [28] - 15:10, 34:16, 37:23, 53:10, 57:24, 77:11, 77:21, 83:17, 91:8, 91:16, 96:15, 116:17, 116:21, 124:6, 124:18, 133:18, 165:15, 169:18, 170:16, 175:8, 175:20, 182:4, 202:10, 215:21, 224:17, 226:19, 244:3 needed [3] - 123:2, 137:19, 149:13 needs [2] - 10:16, 140:9 nerd [1] - 235:25 never [16] - 24:13, 24:15, 26:18, 26:20, 45:17, 45:19, 46:10, 51:10, 51:11, 51:12, 68:15, 86:15, 86:22, 130:19, 130:23, 158:5 New [10] - 3:5, 3:8, 60:20, 88:15, 103:9, 103:11, 107:9, 107:18, 180:20, 216:8 new [12] - 7:23, 34:10, 34:25, 38:3, 38:4, 45:16, 81:21, 81:22, 82:7, 127:20, 158:14, 216:18 newspaper [3] - 74:25, 75:7, 78:6 next [29] - 11:25, 12:1, 28:13, 39:14, 41:17, 47:19, 58:4, 91:15, 92:10, 93:23, 126:5, 128:6, 132:17, 133:11, 135:23, 136:18, 137:25, 138:11, 152:3, 154:25, 174:16,	193:14, 199:24, 206:12, 207:19, 210:21, 210:23, 212:16, 227:6 nice [2] - 155:10, 155:11 NICHOLAS [37] - 6:11, 7:8, 7:11, 7:13, 7:16, 8:19, 8:25, 13:19, 14:4, 15:17, 15:18, 17:24, 18:2, 18:23, 19:7, 19:25, 20:4, 24:19, 24:21, 24:23, 31:21, 32:4, 32:8, 33:18, 33:19, 34:18, 34:20, 34:21, 36:1, 36:6, 36:9, 50:25, 51:16, 63:10, 79:22, 80:9, 95:24 Nicholas [9] - 7:7, 14:3, 15:16, 50:5, 79:16, 79:25, 80:4, 80:8, 80:23 Nicholas's [1] - 79:8 Nigeria [1] - 105:1 night [1] - 18:24 Nike [1] - 238:17 Ninth [1] - 4:6 non [11] - 21:18, 55:19, 88:17, 146:24, 163:14, 177:25, 185:8, 206:14, 231:18, 240:16, 240:17 non-commercial [1] - 240:16 non-contractual [1] - 231:18 non-FDA [1] - 177:25 non-internet [1] - 21:18 non-medical [3] - 88:17, 146:24, 185:8 non-opioid [1] - 206:14 non-prescribed [1] - 163:14 non-profits [1] - 240:17 non-public [1] - 55:19 none [3] - 8:12, 18:25, 60:14 Nonetheless [1] - 195:21 nonprescription [1] - 100:22 noon [1] - 96:13 normal [1] - 189:14 normally [1] - 82:5 Northeast [1] - 180:19
N				
name [16] - 12:10, 52:3, 52:14, 64:6, 70:12, 71:7, 97:8, 104:15, 151:14, 169:22, 175:20, 175:24, 205:21, 227:14, 232:17, 235:16 narcotic [9] - 164:10, 173:21, 176:19, 176:20, 176:25, 177:2, 218:23, 218:24, 219:6 narrow [1] - 115:4 nation's [1] - 147:14 national [27] - 64:23, 88:22, 88:23, 88:25, 89:4, 113:18, 113:19, 119:23, 121:11, 121:19, 123:17, 123:21, 123:23, 124:15, 124:18, 124:21, 128:1, 130:24, 131:7, 194:2, 195:7, 198:6, 198:17,				

<p>Northwestern [1] - 232:16</p> <p>nose [1] - 203:8</p> <p>note [7] - 50:23, 51:8, 60:16, 103:22, 168:19, 168:20, 174:22</p> <p>notes [7] - 33:14, 50:17, 50:19, 51:1, 51:10, 51:12</p> <p>Nothing [1] - 226:9</p> <p>nothing [4] - 13:20, 48:7, 85:9, 168:14</p> <p>notice [10] - 16:11, 16:13, 26:15, 28:22, 43:13, 57:24, 94:24, 95:8, 95:11, 181:16</p> <p>noticed [1] - 66:24</p> <p>noticing [2] - 117:12, 180:20</p> <p>notify [1] - 14:18</p> <p>noting [1] - 88:8</p> <p>notion [2] - 78:24, 79:2</p> <p>notwithstanding [1] - 212:23</p> <p>number [53] - 11:5, 17:14, 20:21, 21:19, 23:14, 23:18, 25:7, 32:1, 84:3, 87:4, 89:17, 101:13, 108:19, 109:19, 116:20, 116:21, 118:20, 122:7, 126:11, 128:14, 128:15, 129:2, 129:5, 131:12, 132:21, 133:24, 134:3, 137:13, 138:1, 138:21, 139:11, 139:19, 152:4, 157:2, 157:15, 159:15, 163:4, 166:24, 167:7, 180:20, 181:8, 181:16, 183:13, 187:19, 188:5, 190:8, 200:9, 212:8, 221:22, 221:24, 222:25, 223:19, 223:20</p> <p>Number [1] - 20:2</p> <p>numbering [1] - 196:25</p> <p>numbers [22] - 40:15, 101:24, 101:25, 102:1, 118:15, 120:15, 127:12, 130:9, 130:22, 139:8, 176:2, 176:4,</p>	<p>180:10, 183:17, 187:20, 188:1, 195:14, 204:25, 206:14, 206:17, 222:2, 223:21</p> <p>numerous [2] - 41:3, 59:7</p> <p>NW [6] - 2:10, 4:6, 4:13, 4:15, 5:5, 5:12</p> <p>NY [1] - 3:5</p> <p style="text-align: center;">O</p> <p>oath [1] - 227:13</p> <p>object [18] - 15:10, 34:16, 46:13, 50:25, 56:18, 57:6, 57:7, 59:15, 63:10, 74:25, 75:21, 79:22, 82:18, 102:8, 140:3, 140:5, 147:24, 153:10</p> <p>objected [2] - 60:17, 80:14</p> <p>objecting [2] - 66:22, 66:23</p> <p>objection [40] - 13:25, 37:2, 43:24, 45:4, 45:16, 48:5, 51:16, 53:19, 54:16, 54:18, 54:22, 55:6, 57:20, 65:15, 65:19, 65:22, 69:8, 70:17, 71:18, 74:5, 75:23, 76:2, 78:11, 80:21, 83:3, 140:11, 168:1, 168:19, 169:6, 171:1, 174:10, 224:16, 225:7, 226:2, 234:19, 234:20, 234:21, 234:22</p> <p>Objection [2] - 13:18, 211:23</p> <p>objectors [1] - 57:7</p> <p>obligation [19] - 27:11, 28:16, 31:6, 31:11, 41:11, 72:25, 73:7, 73:8, 82:4, 84:20, 84:23, 90:5, 92:20, 93:1, 93:7, 93:10, 93:11, 93:21, 227:2</p> <p>obligations [8] - 26:10, 26:11, 41:15, 41:16, 42:25, 43:2, 55:5, 56:15</p> <p>observe [1] - 237:6</p> <p>observed [4] - 158:13, 164:4, 188:4, 195:21</p> <p>obtain [1] - 223:9</p>	<p>obtained [2] - 61:9, 194:8</p> <p>obtaining [1] - 88:16</p> <p>obvious [1] - 117:8</p> <p>obviously [5] - 62:8, 103:2, 137:20, 190:3, 192:11</p> <p>occasionally [1] - 104:17</p> <p>occasions [1] - 59:3</p> <p>Occupational [1] - 101:14</p> <p>occupational [1] - 107:2</p> <p>occur [4] - 29:20, 30:23, 142:10, 142:11</p> <p>occurred [18] - 8:3, 8:9, 8:18, 25:11, 31:8, 33:5, 46:1, 142:22, 143:15, 161:24, 173:6, 173:18, 178:5, 199:22, 200:16, 200:19, 201:10</p> <p>occurs [2] - 59:10, 62:9</p> <p>OCME [1] - 123:3</p> <p>October [1] - 111:25</p> <p>ODCO [2] - 14:16, 14:17</p> <p>OF [2] - 1:1, 1:4</p> <p>offer [12] - 57:22, 80:18, 115:5, 156:2, 157:12, 163:24, 205:6, 213:1, 223:16, 223:18, 224:10, 234:17</p> <p>offered [12] - 28:4, 57:23, 156:10, 156:14, 162:2, 164:12, 169:2, 178:3, 196:11, 211:24, 244:7, 244:8</p> <p>offering [6] - 142:18, 157:1, 157:4, 157:15, 168:11, 169:16</p> <p>offers [2] - 234:15, 238:1</p> <p>Office [19] - 9:7, 9:13, 47:8, 52:8, 52:25, 53:25, 60:18, 81:23, 111:9, 117:15, 123:5, 127:6, 143:16, 143:17, 149:25, 150:1, 160:4, 166:25, 199:15</p> <p>office [4] - 76:13,</p>	<p>76:15, 76:16, 199:16</p> <p>Officer [1] - 104:14</p> <p>Offices [1] - 81:19</p> <p>offices [1] - 91:23</p> <p>Official [2] - 246:2, 246:3</p> <p>official [11] - 54:4, 77:23, 89:13, 90:14, 90:22, 124:11, 125:2, 125:16, 150:5, 150:7, 223:9</p> <p>officials [3] - 64:11, 64:18, 86:10</p> <p>often [3] - 108:22, 113:6, 113:7</p> <p>Often [1] - 237:13</p> <p>Ohio [3] - 36:25, 37:11, 91:4</p> <p>old [5] - 100:23, 112:18, 129:10, 129:11, 129:19</p> <p>omnibus [1] - 170:6</p> <p>on-site [1] - 30:7</p> <p>once [4] - 82:10, 117:11, 167:21</p> <p>one [93] - 7:20, 11:8, 17:25, 19:15, 20:7, 20:13, 20:14, 22:16, 26:24, 28:1, 30:9, 31:16, 31:20, 32:11, 32:19, 34:4, 44:17, 46:4, 46:18, 52:10, 53:3, 53:24, 62:21, 62:22, 63:22, 63:23, 67:9, 69:15, 70:1, 73:4, 77:19, 83:12, 84:24, 84:25, 88:5, 99:8, 100:20, 106:10, 109:20, 117:7, 122:11, 123:19, 124:15, 125:15, 127:4, 127:5, 129:3, 134:12, 136:18, 144:23, 148:15, 148:18, 149:9, 150:9, 151:14, 159:5, 161:4, 162:18, 168:18, 172:24, 172:25, 176:15, 186:19, 187:7, 192:2, 194:10, 202:17, 204:1, 204:15, 205:14, 212:9, 214:23, 216:23, 217:6, 217:7, 217:10, 217:25, 220:3, 220:4, 220:16, 220:18,</p>	<p>227:1, 231:16, 233:6, 237:11, 239:2, 239:3, 242:4, 242:11, 243:22</p> <p>One [4] - 5:11, 8:10, 232:15, 243:21</p> <p>one-quarter [1] - 204:1</p> <p>one-third [2] - 202:17, 204:15</p> <p>ones [2] - 189:22, 189:25</p> <p>ongoing [3] - 141:11, 153:14, 154:17</p> <p>onwards [3] - 100:25, 131:23, 141:1</p> <p>oops [1] - 50:13</p> <p>open [2] - 60:8, 82:3</p> <p>opened [6] - 10:5, 10:6, 21:4, 21:16, 80:7, 82:2</p> <p>opening [1] - 82:3</p> <p>opens [1] - 81:21</p> <p>operate [2] - 72:19, 73:1</p> <p>operating [2] - 81:9, 81:15</p> <p>operation [1] - 82:10</p> <p>operations [2] - 9:17, 14:15</p> <p>opiate [1] - 138:7</p> <p>opined [1] - 173:7</p> <p>opinion [41] - 42:17, 43:25, 120:14, 123:9, 134:12, 141:10, 153:14, 156:2, 157:1, 157:4, 157:12, 157:15, 158:13, 160:13, 161:2, 161:7, 164:12, 176:8, 176:11, 176:17, 176:18, 176:24, 177:9, 189:11, 196:11, 213:4, 218:22, 223:16, 223:18, 236:19, 236:24, 236:25, 237:1, 237:3, 237:4, 239:9, 239:13, 240:20, 240:23, 240:25, 241:9</p> <p>opinions [34] - 115:6, 118:22, 142:18, 148:6, 150:19, 151:10, 153:4, 154:12, 156:4, 156:9, 156:10, 156:14, 158:7, 162:2, 163:18,</p>
---	--	---	--	--

Ayme A. Cochran, RMR, CRR (304) 347-3128

<p>140:17, 140:22, 144:23, 147:7, 175:18, 175:25, 176:14, 176:15, 180:9, 182:24, 184:2, 184:3, 184:4, 184:25, 185:22, 187:13, 187:15, 187:17, 187:18, 187:20, 187:23, 192:22, 193:4, 193:14, 193:16, 194:22, 195:13, 195:14, 195:15, 195:17, 196:9, 196:25, 197:1, 197:2, 217:1, 217:2, 217:20, 218:16, 220:23, 220:24</p> <p>page [27] - 10:3, 37:21, 39:9, 49:4, 49:18, 49:21, 63:23, 74:21, 79:9, 93:23, 129:12, 176:8, 176:10, 192:18, 192:21, 193:3, 193:4, 193:14, 193:25, 199:24, 206:12, 210:1, 210:21, 210:23, 211:7, 212:16, 217:21</p> <p>pages [3] - 18:7, 33:8, 241:12</p> <p>paid [1] - 24:14</p> <p>pain [4] - 62:7, 83:7, 185:8, 212:13</p> <p>pair [1] - 238:16</p> <p>Papantonio [1] - 2:12</p> <p>paper [10] - 148:3, 148:5, 167:10, 200:4, 210:18, 221:6, 243:20, 244:5, 244:11, 244:12</p> <p>Papua [2] - 107:9, 107:18</p> <p>paragraph [30] - 11:25, 12:1, 12:2, 14:11, 14:13, 15:21, 17:1, 26:11, 34:5, 40:9, 40:14, 40:20, 42:22, 46:18, 84:14, 84:15, 84:16, 84:17, 87:4, 88:5, 92:17, 94:17, 95:7, 151:2, 180:15, 185:1, 195:19, 211:11, 211:13, 221:5</p> <p>Paragraph [6] - 24:24,</p>	<p>25:5, 25:14, 29:4, 30:8, 47:4</p> <p>parallels [1] - 237:6</p> <p>part [49] - 18:11, 18:12, 18:20, 25:2, 35:5, 37:14, 38:13, 40:8, 50:8, 86:15, 91:16, 100:15, 101:1, 106:5, 106:6, 106:24, 109:9, 109:12, 110:10, 111:12, 113:22, 115:11, 118:11, 119:1, 119:24, 123:12, 123:19, 125:19, 126:7, 128:4, 130:11, 130:19, 141:24, 142:20, 147:3, 147:8, 148:5, 149:10, 150:9, 160:12, 172:7, 181:11, 189:12, 197:5, 224:25, 225:9, 231:3, 237:16, 240:11</p> <p>Part [3] - 172:17, 189:10, 234:10</p> <p>partially [1] - 59:24</p> <p>participants [1] - 70:12</p> <p>Participants [1] - 182:24</p> <p>participated [2] - 71:2, 71:4</p> <p>particular [34] - 8:17, 14:25, 20:24, 20:25, 49:18, 54:11, 71:8, 72:6, 82:8, 90:10, 99:8, 104:19, 110:1, 111:11, 113:13, 114:10, 114:14, 114:23, 114:24, 116:16, 126:15, 130:25, 137:19, 153:20, 190:2, 210:15, 215:23, 229:17, 235:14, 240:10, 240:12, 240:15, 241:4</p> <p>particularly [11] - 55:20, 80:2, 109:21, 110:19, 110:25, 112:3, 115:2, 117:13, 130:12, 147:1, 230:6</p> <p>parties [4] - 17:10, 25:22, 31:13, 31:16</p> <p>partner [2] - 232:2, 236:12</p>	<p>partnership [1] - 232:4</p> <p>parts [3] - 60:25, 100:20, 159:4</p> <p>party [5] - 17:4, 17:10, 26:15, 28:25, 30:16</p> <p>passion [1] - 233:20</p> <p>past [4] - 56:22, 143:25, 229:9, 233:3</p> <p>paste [1] - 193:6</p> <p>patches [3] - 140:25, 181:22, 181:23</p> <p>path [1] - 197:17</p> <p>pathologist [1] - 123:10</p> <p>patience [1] - 171:16</p> <p>patient [6] - 98:10, 106:11, 108:5, 162:15, 162:23, 162:25</p> <p>patient's [1] - 94:4</p> <p>patients [3] - 94:1, 94:9, 163:1</p> <p>pattern [5] - 30:14, 197:15, 209:25, 210:3, 218:3</p> <p>patterns [1] - 195:21</p> <p>Patterns [2] - 144:2, 220:13</p> <p>PAUL [2] - 2:3, 5:9</p> <p>Pause [5] - 36:3, 61:3, 69:16, 97:3, 154:10</p> <p>pay [1] - 24:10</p> <p>PDAC [3] - 58:14, 59:8, 59:10</p> <p>pdf [1] - 129:10</p> <p>PDMP [3] - 151:16, 186:9, 187:11</p> <p>PDMPs [1] - 212:14</p> <p>PEARL [1] - 3:6</p> <p>peek [1] - 210:8</p> <p>peer [1] - 121:6</p> <p>pending [2] - 65:18, 243:20</p> <p>Pensacola [1] - 2:14</p> <p>people [44] - 30:24, 59:9, 62:4, 98:13, 99:12, 99:24, 101:12, 104:16, 104:18, 108:19, 109:9, 109:24, 110:14, 111:4, 112:2, 112:17, 113:9, 118:15, 122:24, 125:9, 125:14, 127:5, 129:20, 129:21, 133:19, 133:24, 135:17, 136:16, 144:17, 144:20,</p>	<p>149:9, 151:21, 152:19, 164:25, 181:22, 185:24, 192:10, 194:3, 232:24, 235:16, 237:13, 239:21, 240:1</p> <p>people's [2] - 240:11, 244:23</p> <p>per [9] - 139:24, 140:14, 188:6, 188:7, 194:3, 194:6, 195:2, 195:9, 198:10</p> <p>percent [25] - 134:10, 135:11, 135:12, 135:14, 146:7, 146:8, 146:10, 146:21, 146:24, 147:3, 147:4, 147:5, 151:18, 152:10, 152:12, 152:19, 186:7, 186:14, 186:16, 188:15, 190:15, 220:3, 220:4</p> <p>percentage [4] - 134:7, 134:9, 139:19, 186:11</p> <p>perceptions [1] - 240:10</p> <p>perfect [3] - 36:6, 40:10, 40:17</p> <p>perform [1] - 235:22</p> <p>performance [1] - 110:2</p> <p>performed [1] - 241:20</p> <p>perhaps [1] - 204:18</p> <p>period [54] - 10:12, 26:12, 27:2, 28:11, 45:6, 47:20, 47:22, 53:25, 116:3, 116:24, 117:24, 132:13, 132:14, 133:3, 136:14, 136:15, 137:22, 138:17, 141:16, 144:13, 146:14, 156:9, 156:10, 156:15, 157:3, 157:16, 158:8, 161:24, 164:14, 165:7, 173:7, 177:18, 179:17, 181:7, 192:14, 194:8, 195:7, 196:19, 199:19, 201:25, 202:3, 204:5, 206:7, 206:22, 207:11, 207:24, 208:7,</p>	<p>208:15, 208:24, 218:3, 220:5, 221:9, 223:17</p> <p>periodicals [1] - 233:10</p> <p>periods [5] - 126:9, 131:4, 140:25, 197:12, 222:18</p> <p>permanent [2] - 104:2, 104:4</p> <p>permission [6] - 168:8, 168:22, 174:4, 174:9, 205:15</p> <p>permitted [1] - 22:18</p> <p>person [6] - 76:13, 109:12, 122:19, 122:22, 143:20, 155:10</p> <p>person's [1] - 150:2</p> <p>personal [4] - 69:13, 90:9, 90:10, 174:3</p> <p>personally [3] - 125:7, 149:10, 165:2</p> <p>personnel [2] - 7:19, 120:11</p> <p>persons [2] - 185:8, 214:7</p> <p>perspective [2] - 136:23, 238:15</p> <p>persuade [2] - 240:6, 240:8</p> <p>pertussis [1] - 104:25</p> <p>PETER [1] - 2:12</p> <p>Ph.D [6] - 229:11, 229:13, 229:18, 229:21, 230:20, 233:23</p> <p>pharmaceutical [20] - 88:17, 144:18, 145:21, 146:9, 183:3, 183:7, 183:10, 235:6, 235:9, 235:15, 235:24, 236:1, 236:2, 237:7, 237:21, 239:11, 239:14, 239:16, 241:19</p> <p>Pharmaceutical [2] - 144:3, 220:14</p> <p>pharmaceuticals [1] - 235:19</p> <p>pharmacies [42] - 9:20, 9:21, 9:23, 10:8, 10:12, 10:14, 10:15, 10:16, 10:21, 11:1, 11:10, 11:11, 11:15, 13:4, 16:8, 17:6, 23:11, 23:12, 23:13, 23:14, 23:15,</p>
---	---	---	--	---

<p>23:21, 34:12, 35:1, 47:23, 59:8, 60:12, 62:4, 64:14, 64:15, 64:19, 79:17, 80:3, 81:5, 81:12, 82:23, 86:11, 87:7, 87:8, 87:11, 87:18, 187:3</p> <p>Pharmacist [1] - 81:13</p> <p>pharmacists [2] - 59:8, 60:20</p> <p>pharmacy [37] - 10:18, 10:19, 10:23, 10:24, 10:25, 12:10, 12:15, 12:16, 12:22, 12:25, 13:3, 13:15, 14:16, 15:9, 16:2, 20:10, 20:11, 20:22, 37:16, 39:17, 49:24, 81:7, 81:8, 81:9, 81:15, 81:20, 81:21, 81:22, 82:2, 82:3, 82:6, 82:8, 82:14, 155:23</p> <p>Pharmacy [1] - 58:14</p> <p>Phil [1] - 52:13</p> <p>Philadelphia [2] - 6:6, 6:13</p> <p>photographs [1] - 123:1</p> <p>physical [1] - 165:11</p> <p>physician [12] - 84:24, 98:11, 122:21, 162:6, 162:7, 162:10, 162:11, 162:13, 162:18, 163:10, 235:16</p> <p>physicians [9] - 84:3, 84:5, 84:21, 85:2, 92:21, 93:2, 93:13, 93:25, 94:3</p> <p>pick [2] - 155:12, 243:8</p> <p>picked [3] - 35:10, 134:22, 158:7</p> <p>picking [4] - 67:2, 68:11, 69:6, 70:2</p> <p>picks [1] - 95:7</p> <p>picture [2] - 238:23, 238:24</p> <p>pictures [1] - 214:25</p> <p>piece [7] - 48:14, 111:16, 115:8, 131:2, 143:19, 145:23, 164:24</p> <p>PIFKO [1] - 3:16</p> <p>pills [3] - 23:6, 154:6</p> <p>pink [2] - 201:14, 201:20</p> <p>pinnacle [2] - 108:25, 109:2</p> <p>place [6] - 9:12, 108:2,</p>	<p>111:11, 118:25, 242:6, 242:9</p> <p>placed [3] - 47:23, 87:7, 123:21</p> <p>places [4] - 107:9, 204:25, 216:9, 238:21</p> <p>plain [1] - 29:13</p> <p>Plaintiff [5] - 1:5, 1:11, 2:2, 3:2, 4:1</p> <p>PLAINTIFF [1] - 97:12</p> <p>Plaintiffs [1] - 246:6</p> <p>plaintiffs [7] - 46:15, 60:16, 97:4, 114:6, 155:15, 227:10, 244:2</p> <p>Plaintiffs' [1] - 186:3</p> <p>plaintiffs' [8] - 86:23, 156:19, 165:18, 178:10, 182:17, 199:7, 199:11, 243:23</p> <p>PLAINTIFFS' [1] - 227:18</p> <p>plan [2] - 73:11, 73:14</p> <p>planning [3] - 150:17, 242:19, 242:20</p> <p>plans [2] - 111:15, 244:23</p> <p>plant [1] - 234:14</p> <p>play [4] - 153:5, 153:21, 239:15</p> <p>playing [1] - 141:24</p> <p>Pleasant [3] - 3:15, 4:4, 4:9</p> <p>pleasantly [1] - 36:19</p> <p>plot [1] - 215:16</p> <p>plugging [1] - 107:13</p> <p>plus [1] - 151:7</p> <p>pockets [1] - 85:2</p> <p>point [46] - 10:3, 11:9, 13:5, 22:16, 33:5, 33:23, 35:7, 40:4, 41:13, 53:3, 56:6, 58:4, 78:4, 79:21, 81:1, 91:20, 92:3, 113:4, 113:8, 116:18, 133:18, 136:1, 137:4, 141:21, 150:15, 151:12, 168:5, 170:4, 170:12, 170:15, 175:7, 175:9, 182:5, 192:19, 214:15, 214:18, 215:1, 216:12, 218:6, 218:11, 218:21, 230:3, 230:12, 230:19, 244:10</p>	<p>points [2] - 10:2, 11:6</p> <p>poisoning [24] - 100:4, 117:25, 118:7, 118:8, 118:11, 125:6, 126:14, 126:18, 127:7, 127:23, 129:1, 130:7, 131:24, 147:15, 147:16, 148:2, 156:11, 156:20, 160:12, 183:23, 194:25, 195:8</p> <p>poisonings [22] - 100:7, 100:18, 106:23, 118:12, 118:14, 126:7, 126:23, 127:4, 127:8, 127:25, 130:5, 130:16, 156:19, 156:23, 156:24, 157:2, 157:5, 157:6, 192:25, 198:9</p> <p>police [1] - 40:24</p> <p>policies [5] - 16:23, 44:24, 76:16, 76:17, 111:15</p> <p>policy [13] - 14:25, 15:4, 15:22, 15:24, 30:22, 44:16, 55:25, 56:1, 56:21, 56:22, 56:24, 77:6, 92:11</p> <p>poly [2] - 201:1</p> <p>polypharmacy [6] - 160:23, 161:20, 188:3, 188:11, 201:3, 224:4</p> <p>Polypharmacy [2] - 187:16, 188:1</p> <p>Ponc [1] - 2:4</p> <p>Ponce [1] - 2:16</p> <p>poor [1] - 236:12</p> <p>pop [1] - 154:5</p> <p>population [9] - 98:19, 103:13, 129:22, 129:23, 129:25, 183:2, 183:7, 186:21, 195:2</p> <p>portion [2] - 44:16, 206:12</p> <p>portions [2] - 48:6, 59:25</p> <p>portraying [1] - 90:3</p> <p>pose [1] - 68:20</p> <p>position [19] - 7:18, 16:9, 43:7, 54:4, 55:2, 55:12, 56:7, 56:13, 58:1, 61:15, 61:18, 89:12, 90:4,</p>	<p>90:19, 90:21, 149:7, 162:13, 162:22</p> <p>positions [2] - 43:13, 94:23</p> <p>possibility [3] - 176:19, 218:23, 219:7</p> <p>possible [3] - 157:14, 214:3, 228:6</p> <p>post-2018 [1] - 222:14</p> <p>Powell [1] - 2:6</p> <p>PowerPoint [16] - 10:7, 18:1, 18:3, 18:7, 18:8, 18:13, 18:15, 18:17, 19:2, 50:8, 50:16, 50:18, 58:13, 58:25, 59:13, 59:21</p> <p>PR [2] - 2:5, 2:17</p> <p>practice [3] - 27:4, 129:17, 160:3</p> <p>practices [2] - 40:6, 162:16</p> <p>practicing [2] - 162:6, 162:7</p> <p>pre-1999 [1] - 225:2</p> <p>pre-2001 [1] - 127:18</p> <p>predecessors [1] - 52:10</p> <p>predicate [1] - 29:10</p> <p>predictable [3] - 195:20, 197:15, 210:3</p> <p>preliminary [7] - 221:19, 222:1, 223:8, 223:13, 223:18, 223:24</p> <p>preparation [1] - 192:16</p> <p>prepare [6] - 228:7, 229:20, 236:13, 236:16, 237:22, 242:21</p> <p>prepared [3] - 132:15, 228:16, 232:10</p> <p>preparing [1] - 180:6</p> <p>prescribe [2] - 84:3, 162:8</p> <p>prescribed [10] - 147:6, 151:21, 152:20, 163:10, 163:14, 163:19, 186:12, 212:17, 212:19, 213:11</p> <p>prescriber [7] - 39:17, 91:3, 91:20, 92:1, 92:2, 163:10, 187:5</p> <p>prescribing [3] - 162:13, 162:14, 197:11</p>	<p>Prescription [3] - 143:21, 150:2, 151:13</p> <p>prescription [104] - 99:19, 100:21, 134:16, 136:8, 136:12, 136:13, 137:23, 138:6, 138:18, 138:21, 138:22, 141:6, 141:11, 141:15, 141:20, 141:24, 142:9, 142:19, 143:23, 143:24, 144:20, 144:21, 146:14, 148:11, 148:13, 150:2, 151:19, 151:24, 151:25, 152:1, 152:10, 152:11, 152:15, 152:17, 152:18, 153:4, 153:15, 153:19, 153:20, 154:2, 154:6, 154:19, 155:20, 157:16, 158:2, 162:3, 162:5, 163:5, 163:8, 163:9, 163:13, 163:19, 164:4, 166:10, 166:19, 167:5, 170:7, 173:4, 177:4, 177:22, 178:5, 178:24, 179:3, 181:21, 184:7, 184:9, 185:8, 187:4, 187:8, 189:7, 189:9, 189:13, 189:20, 189:23, 190:5, 190:7, 190:9, 190:12, 190:13, 211:14, 211:18, 212:8, 212:18, 213:10, 213:19, 214:2, 215:3, 215:11, 215:15, 215:25, 216:10, 216:11, 216:14, 216:22, 217:5, 217:12, 220:22, 221:12, 223:4, 223:6, 224:6, 236:21</p> <p>prescriptions [4] - 10:22, 146:17, 186:9, 186:20</p> <p>presence [6] - 141:14, 142:9, 176:18, 218:23, 219:6</p> <p>present [5] - 42:25, 90:21, 102:16,</p>
---	--	--	--	---

<p>215:25, 224:12</p> <p>presentation [35] - 12:3, 18:13, 18:15, 19:3, 35:9, 35:13, 35:14, 49:25, 50:2, 51:10, 51:11, 58:13, 58:17, 58:20, 58:21, 58:22, 59:3, 59:6, 59:11, 60:12, 60:13, 60:20, 66:12, 79:10, 79:13, 79:20, 79:23, 80:2, 80:4, 80:13, 81:5, 88:16, 89:16, 89:19</p> <p>presentations [5] - 19:1, 35:5, 35:20, 66:16, 89:23</p> <p>presented [6] - 12:9, 32:13, 80:12, 199:16, 224:14, 224:23</p> <p>presenter [1] - 35:10</p> <p>presenters [1] - 34:1</p> <p>presenting [3] - 10:6, 12:21, 12:22</p> <p>press [3] - 76:24, 77:4, 119:8</p> <p>presumably [1] - 12:10</p> <p>pretend [1] - 218:21</p> <p>pretty [2] - 19:9, 30:23</p> <p>prevalence [3] - 146:15, 177:15, 181:1</p> <p>prevalent [1] - 147:1</p> <p>prevent [3] - 30:13, 107:3, 107:4</p> <p>Prevention [1] - 192:5</p> <p>prevention [7] - 98:15, 99:10, 106:2, 106:7, 107:14, 109:14, 112:11</p> <p>preventive [1] - 104:21</p> <p>prevents [1] - 41:14</p> <p>previous [2] - 139:22, 217:21</p> <p>previously [5] - 50:11, 52:22, 54:10, 54:11, 160:21</p> <p>Prevoznik [2] - 8:13, 8:14</p> <p>pricing [1] - 237:16</p> <p>primarily [1] - 196:12</p> <p>primary [1] - 221:9</p> <p>principal [1] - 106:15</p> <p>Principles [1] - 229:5</p> <p>printer [1] - 234:12</p> <p>privilege [1] - 55:18</p> <p>privileged [2] - 15:13,</p>	<p>55:17</p> <p>problem [36] - 29:25, 40:25, 55:10, 64:23, 66:8, 77:19, 77:20, 99:14, 109:8, 109:15, 110:25, 112:14, 113:8, 115:2, 115:3, 115:9, 115:10, 115:13, 116:6, 127:20, 133:2, 136:11, 140:10, 143:12, 152:16, 168:24, 181:12, 198:2, 198:19, 198:20, 216:7, 216:8, 216:22, 217:14, 218:7, 245:2</p> <p>problems [9] - 30:3, 30:6, 104:19, 104:24, 110:21, 111:1, 112:3, 216:3</p> <p>procedures [4] - 16:24, 76:17, 82:5, 82:11</p> <p>proceed [4] - 85:11, 85:12, 155:4, 182:13</p> <p>proceeding [2] - 42:8, 64:3</p> <p>proceedings [1] - 246:5</p> <p>Proceedings [1] - 6:19</p> <p>PROCEEDINGS [1] - 7:1</p> <p>process [18] - 15:1, 16:1, 16:3, 16:5, 16:6, 18:11, 27:17, 73:14, 124:2, 124:3, 128:9, 132:4, 145:24, 197:5, 210:2, 242:20</p> <p>Proctor [1] - 2:12</p> <p>produce [1] - 127:10</p> <p>produced [4] - 6:19, 165:6, 181:2, 204:23</p> <p>produces [1] - 127:6</p> <p>product [6] - 231:5, 237:16, 238:15, 238:19, 240:12, 240:15</p> <p>Products [1] - 229:7</p> <p>products [3] - 230:11, 231:1, 240:1</p> <p>professional [6] - 64:10, 108:9, 122:24, 123:9, 154:13, 228:25</p> <p>professionals [1] - 221:11</p>	<p>professor [3] - 101:4, 101:8, 232:16</p> <p>Professor [11] - 98:3, 101:5, 106:19, 106:20, 108:16, 227:25, 228:18, 228:21, 228:23, 229:2</p> <p>profile [1] - 12:9</p> <p>profits [1] - 240:17</p> <p>Program [6] - 29:9, 73:18, 101:14, 143:21, 150:3, 151:15</p> <p>program [9] - 30:12, 44:19, 44:20, 66:17, 88:5, 103:17, 104:9, 106:25, 122:10</p> <p>Programs [1] - 151:13</p> <p>progress [1] - 112:1</p> <p>prohibited [1] - 170:8</p> <p>prohibiting [1] - 15:4</p> <p>project [4] - 104:11, 111:13, 111:23, 236:4</p> <p>projects [6] - 101:6, 101:13, 106:22, 108:20, 109:19, 110:18</p> <p>promise [2] - 80:25, 155:13</p> <p>promises [2] - 67:25, 121:5</p> <p>prompting [1] - 102:11</p> <p>proper [4] - 82:14, 82:15, 83:2, 102:10</p> <p>properly [2] - 80:23, 224:18</p> <p>proportion [3] - 223:4, 224:3, 224:5</p> <p>proposed [3] - 64:2, 64:6, 85:25</p> <p>protect [1] - 174:6</p> <p>protocols [1] - 16:23</p> <p>provide [12] - 15:7, 25:18, 35:11, 59:22, 120:14, 135:3, 139:19, 168:8, 185:17, 230:11, 237:13, 237:19</p> <p>provided [9] - 50:11, 52:22, 66:13, 101:19, 130:3, 159:11, 169:20, 170:20, 199:14</p> <p>provides [3] - 33:11, 85:6, 121:22</p> <p>providing [4] - 34:9, 34:24, 79:3, 239:5</p>	<p>provision [2] - 28:2, 46:4</p> <p>provisional [1] - 183:18</p> <p>proximity [1] - 32:22</p> <p>psychiatrist [1] - 213:3</p> <p>psychotherapeutic [3] - 184:7, 184:16, 184:18</p> <p>Pub [1] - 98:22</p> <p>public [42] - 15:11, 55:19, 59:19, 60:2, 60:10, 60:11, 60:13, 60:18, 60:19, 60:22, 89:20, 89:23, 90:3, 90:18, 93:5, 93:12, 93:23, 97:23, 98:5, 98:16, 99:14, 100:1, 104:8, 105:22, 105:23, 105:24, 106:1, 106:2, 106:5, 106:6, 106:9, 107:7, 107:8, 108:10, 112:16, 169:13, 169:25, 170:1, 174:23, 175:2, 175:6</p> <p>Public [13] - 97:24, 98:4, 101:11, 101:12, 104:5, 104:6, 104:12, 105:12, 105:18, 106:21, 107:6, 108:13, 108:18</p> <p>publication [3] - 149:18, 150:10, 191:16</p> <p>publications [1] - 112:15</p> <p>publicly [1] - 59:21</p> <p>publish [1] - 228:13</p> <p>published [15] - 112:6, 121:7, 142:14, 142:25, 143:9, 143:10, 144:3, 146:5, 148:14, 191:10, 191:13, 231:6, 231:12, 231:15, 231:24</p> <p>pull [10] - 40:14, 41:22, 45:11, 83:17, 83:23, 122:14, 122:15, 199:6, 205:17, 237:24</p> <p>pulled [1] - 238:24</p> <p>pump [3] - 99:9, 99:12, 106:10</p> <p>Purchase [6] - 49:1, 53:1, 53:4, 54:13,</p>	<p>55:4, 56:14</p> <p>purchase [1] - 230:12</p> <p>purchasing [6] - 21:5, 62:4, 62:5, 62:6, 62:7, 240:2</p> <p>pure [2] - 55:9, 78:7</p> <p>purportedly [1] - 77:17</p> <p>purporting [1] - 75:1</p> <p>purpose [9] - 9:19, 41:9, 57:2, 60:7, 147:11, 150:11, 150:12, 169:1, 239:24</p> <p>purposes [6] - 37:19, 84:25, 168:9, 178:3, 240:14, 240:18</p> <p>pursuant [4] - 26:4, 28:21, 59:19, 187:9</p> <p>purveyor [1] - 118:2</p> <p>push [1] - 231:4</p> <p>put [30] - 8:19, 18:20, 18:24, 21:19, 28:2, 29:13, 33:13, 33:14, 44:17, 58:1, 58:3, 65:9, 78:24, 79:2, 85:18, 99:6, 114:18, 122:6, 122:14, 128:2, 131:12, 132:6, 149:1, 177:8, 194:18, 225:14, 225:16, 228:10, 243:20, 244:15</p> <p>putting [2] - 224:13, 225:17</p>
Q				
<p>qualifications [5] - 101:20, 102:21, 108:8, 112:23, 213:7</p> <p>qualified [2] - 114:17, 212:25</p> <p>qualifies [1] - 174:23</p> <p>quantities [4] - 62:6, 62:8, 166:2, 166:9</p> <p>quarter [1] - 204:1</p> <p>quarters [1] - 161:23</p> <p>questioned [3] - 41:23, 62:15, 83:12</p> <p>pull [10] - 40:14, 41:22, 45:11, 83:17, 83:23, 122:14, 122:15, 199:6, 205:17, 237:24</p> <p>pulled [1] - 238:24</p> <p>pump [3] - 99:9, 99:12, 106:10</p> <p>Purchase [6] - 49:1, 53:1, 53:4, 54:13,</p>				

<p>19:11, 19:12, 19:15, 19:17, 19:20, 19:22, 28:1, 40:10, 41:6, 48:10, 48:21, 61:12, 72:11, 80:23, 88:14, 88:19, 91:15, 95:21, 95:24, 112:24, 119:21, 136:23, 154:22, 156:9, 199:3, 205:9, 209:6, 209:9, 209:16, 215:21, 219:20, 221:16, 222:9, 240:23, 242:8</p> <p>quick [1] - 28:11</p> <p>quicker [1] - 28:9</p> <p>quickly [9] - 16:25, 24:24, 64:9, 72:1, 102:21, 102:23, 106:17, 110:16, 206:18</p> <p>quite [3] - 52:9, 161:20, 241:12</p> <p>quotation [2] - 93:17, 93:18</p> <p>quote [4] - 43:1, 75:1, 78:23, 93:13</p> <p>quote/unquote [1] - 10:24</p> <p>quoted [1] - 186:10</p>	<p>85:15, 90:8, 95:23, 95:25, 96:1, 96:4, 96:5, 96:19</p> <p>Rannazzisi's [5] - 37:23, 45:24, 46:20, 78:12, 243:22</p> <p>rapidly [1] - 124:7</p> <p>rare [2] - 177:10, 228:22</p> <p>rate [22] - 110:23, 129:7, 129:16, 129:17, 129:22, 139:4, 139:21, 139:23, 156:11, 186:15, 186:19, 192:24, 194:3, 194:6, 195:4, 195:8, 196:15, 197:13, 198:9, 200:23, 204:1, 223:16</p> <p>rates [15] - 129:15, 129:24, 130:9, 131:5, 131:17, 131:25, 140:13, 147:23, 194:25, 195:1, 195:22, 197:21, 198:13, 216:15, 220:19</p> <p>rather [8] - 43:1, 57:23, 73:1, 108:4, 116:21, 160:15, 164:20, 224:21</p> <p>raw [5] - 27:14, 27:17, 27:19, 28:6, 165:9</p> <p>RE [1] - 85:13</p> <p>re [9] - 37:6, 42:25, 85:10, 88:1, 88:14, 91:9, 92:2, 92:13, 95:3</p> <p>re-cross [1] - 85:10</p> <p>RE-CROSS [1] - 85:13</p> <p>re-direct [5] - 88:1, 88:14, 91:9, 92:13, 95:3</p> <p>re-registration [1] - 92:2</p> <p>re-state [2] - 37:6, 42:25</p> <p>reached [1] - 45:10</p> <p>reaching [2] - 163:16, 164:2</p> <p>reacted [1] - 171:6</p> <p>reaction [2] - 75:19, 75:24</p> <p>read [58] - 10:10, 17:2, 30:9, 34:6, 34:22, 38:1, 38:8, 38:20, 39:2, 39:14, 39:20, 40:8, 40:13, 40:19, 42:2, 42:3, 42:11,</p>	<p>42:22, 43:5, 43:16, 46:8, 47:5, 47:12, 47:17, 48:3, 64:2, 64:9, 65:3, 72:18, 74:20, 75:14, 80:18, 84:16, 84:17, 85:25, 91:3, 91:24, 92:18, 93:17, 93:20, 104:17, 146:3, 152:6, 152:8, 160:7, 175:20, 184:17, 184:20, 185:23, 185:24, 191:24, 217:25, 220:17, 221:5, 236:1, 236:3, 236:8, 244:17</p> <p>reading [22] - 29:5, 40:16, 48:6, 48:12, 59:25, 68:14, 75:11, 75:13, 76:21, 78:23, 91:13, 116:15, 135:19, 140:5, 153:17, 184:25, 193:9, 213:14, 213:17, 214:16, 236:11</p> <p>reads [10] - 34:8, 171:24, 172:14, 173:21, 176:8, 176:18, 180:15, 184:6, 188:2, 195:19</p> <p>ready [2] - 85:12, 226:21</p> <p>real [1] - 101:24</p> <p>realized [2] - 104:7, 107:11</p> <p>really [31] - 18:6, 28:4, 34:4, 72:1, 98:8, 101:23, 105:19, 107:8, 107:14, 108:7, 108:25, 111:9, 112:1, 115:9, 127:12, 127:17, 133:18, 136:3, 142:21, 144:6, 145:23, 148:12, 181:11, 191:17, 217:13, 217:16, 221:25, 239:6, 240:15, 243:3</p> <p>reason [13] - 11:24, 23:16, 27:10, 58:3, 64:17, 86:9, 96:21, 125:25, 169:13, 184:13, 185:21, 237:18, 238:22</p> <p>reasonable [1] - 154:13</p> <p>reasonably [3] - 25:22, 242:16, 243:1</p>	<p>reasoning [1] - 95:6</p> <p>reasons [3] - 33:13, 45:21, 126:25</p> <p>recalled [3] - 71:16, 244:7, 244:9</p> <p>receive [4] - 88:9, 229:13, 234:1, 234:8</p> <p>received [4] - 66:2, 185:11, 232:20, 234:9</p> <p>receiving [2] - 26:4, 185:9</p> <p>recent [8] - 132:15, 142:11, 199:4, 204:9, 205:4, 210:5, 220:18, 230:4</p> <p>recently [3] - 112:12, 188:22, 216:6</p> <p>recess [3] - 119:10, 119:13, 182:7</p> <p>Recess [3] - 36:13, 119:15, 182:12</p> <p>recessed [1] - 245:6</p> <p>reciting [1] - 82:19</p> <p>recognize [13] - 9:3, 49:5, 49:20, 49:23, 50:17, 51:8, 52:3, 52:14, 58:9, 58:12, 58:19, 85:21, 226:19</p> <p>recognized [1] - 216:6</p> <p>recollection [2] - 13:14, 140:4</p> <p>reconcile [1] - 27:19</p> <p>reconciled [2] - 28:7, 28:12</p> <p>reconciliation [2] - 27:17, 28:8</p> <p>reconstruct [1] - 118:6</p> <p>record [46] - 19:25, 28:15, 29:6, 32:3, 34:16, 38:17, 46:9, 48:12, 57:21, 57:25, 58:2, 58:3, 59:19, 60:1, 60:3, 60:10, 60:11, 60:13, 60:18, 60:19, 60:22, 75:13, 86:1, 135:8, 135:16, 140:5, 143:20, 144:1, 146:4, 150:2, 152:8, 152:10, 161:13, 167:25, 168:10, 169:13, 169:25, 171:3, 174:2, 174:23, 175:2, 175:23, 214:16, 225:23, 246:5</p> <p>recorded [5] - 6:19, 123:20, 132:7,</p>	<p>133:16, 133:24</p> <p>recording [1] - 190:18</p> <p>records [9] - 77:21, 92:1, 123:6, 130:21, 142:2, 147:21, 147:22, 167:21, 179:8</p> <p>recross [1] - 222:10</p> <p>RECROSS [1] - 222:12</p> <p>recruit [1] - 108:22</p> <p>red [1] - 136:12</p> <p>redacted [5] - 168:9, 168:23, 171:3, 174:6, 174:8</p> <p>redacts [1] - 168:7</p> <p>redirect [1] - 209:7</p> <p>REDIRECT [2] - 209:10, 219:23</p> <p>reduced [2] - 213:19, 214:2</p> <p>reduction [1] - 212:17</p> <p>Reed [2] - 6:4, 6:11</p> <p>refer [6] - 32:23, 63:22, 70:16, 79:21, 116:17, 116:22</p> <p>reference [4] - 148:19, 185:15, 194:15, 194:19</p> <p>referenced [5] - 156:4, 177:15, 187:7, 190:5, 193:23</p> <p>referencing [5] - 161:9, 204:20, 222:21, 222:22, 223:1</p> <p>referred [3] - 53:23, 185:15, 201:13</p> <p>referring [3] - 62:2, 79:9, 147:19</p> <p>refers [1] - 54:12</p> <p>reflect [8] - 40:5, 41:9, 43:18, 54:4, 65:5, 77:5, 77:9, 174:19</p> <p>reflected [4] - 173:2, 176:24, 193:14, 193:24</p> <p>reflects [3] - 77:10, 203:15, 206:1</p> <p>reformulation [1] - 212:10</p> <p>refreshing [1] - 140:4</p> <p>regard [3] - 51:1, 221:22, 245:2</p> <p>regarding [19] - 15:8, 16:17, 40:9, 43:22, 44:15, 53:1, 54:13, 64:10, 64:12, 64:23, 76:9, 76:14, 91:3, 94:2, 121:22, 146:5,</p>
R				
<p>Rafalski [2] - 243:21, 244:7</p> <p>Rafferty [1] - 2:12</p> <p>raise [2] - 97:10, 227:16</p> <p>Rannazzisi [72] - 7:12, 7:17, 9:1, 15:20, 20:5, 25:7, 27:5, 29:7, 36:9, 36:21, 38:6, 38:10, 38:20, 39:20, 40:16, 41:24, 42:3, 42:6, 42:14, 43:22, 46:5, 46:18, 46:19, 46:24, 48:15, 48:25, 51:1, 51:25, 53:13, 53:22, 55:1, 56:10, 56:21, 58:9, 59:14, 59:20, 61:6, 63:13, 63:19, 64:1, 66:1, 68:7, 69:3, 69:18, 70:9, 70:24, 71:25, 72:11, 73:21, 74:18, 75:5, 75:18, 77:9, 78:23, 79:8, 79:14, 79:23, 80:1, 80:3, 80:6, 81:3, 83:5, 83:22, 85:3,</p>				

<p>148:24, 153:14, 225:22</p> <p>Regardless [1] - 218:25</p> <p>regardless [1] - 130:13</p> <p>regards [10] - 15:14, 112:10, 121:20, 122:1, 122:4, 135:4, 139:19, 142:2, 148:10, 153:15</p> <p>Regents [4] - 228:4, 228:18, 228:21, 229:2</p> <p>region [1] - 221:9</p> <p>Regional [2] - 111:19, 111:22</p> <p>Register [1] - 41:18</p> <p>register [1] - 173:16</p> <p>registered [2] - 10:23, 47:9</p> <p>registrant [7] - 16:2, 43:8, 72:19, 72:20, 73:1, 73:10, 73:15</p> <p>registrant's [1] - 73:7</p> <p>registrants [5] - 43:3, 48:19, 50:11, 52:23, 73:23</p> <p>registrants' [2] - 55:5, 56:15</p> <p>registration [9] - 29:23, 64:17, 84:21, 84:24, 86:10, 91:3, 91:21, 92:2, 92:21</p> <p>registrations [2] - 37:16, 82:15</p> <p>regular [1] - 195:20</p> <p>regularly [2] - 100:17, 197:14</p> <p>regulation [4] - 72:17, 72:18, 73:3, 73:4</p> <p>regulations [3] - 43:1, 43:2, 43:4</p> <p>regulatory [3] - 30:22, 72:13, 72:22</p> <p>rejected [1] - 95:9</p> <p>relate [1] - 170:6</p> <p>related [44] - 30:14, 44:7, 46:4, 55:12, 61:9, 63:21, 99:17, 106:22, 108:10, 112:8, 113:20, 117:13, 133:12, 133:15, 133:16, 134:1, 134:5, 134:10, 137:1, 156:19, 156:23, 156:24, 157:2, 157:5, 159:8, 166:18, 166:19,</p>	<p>167:6, 173:8, 173:25, 177:20, 178:4, 178:5, 178:12, 179:3, 180:22, 182:1, 204:4, 204:14, 221:23, 221:24, 233:10, 243:2</p> <p>relates [5] - 45:23, 46:18, 71:17, 99:22, 191:22</p> <p>relating [1] - 42:3</p> <p>relationship [6] - 81:6, 82:13, 156:3, 211:18, 211:25, 213:22</p> <p>Relationships [1] - 232:25</p> <p>relationships [1] - 82:7</p> <p>relative [2] - 185:10, 185:11</p> <p>relatively [4] - 130:8, 155:14, 164:13, 177:10</p> <p>relatives [1] - 221:2</p> <p>relayed [1] - 70:4</p> <p>release [1] - 127:1</p> <p>released [1] - 149:12</p> <p>relevance [2] - 78:11, 244:8</p> <p>relevant [3] - 78:13, 113:20, 170:23</p> <p>reliability [2] - 170:23, 175:1</p> <p>reliable [12] - 120:14, 120:22, 121:25, 122:2, 122:12, 138:6, 145:25, 146:2, 159:25, 192:7, 192:8, 223:15</p> <p>relied [7] - 142:18, 151:10, 158:22, 164:16, 164:18, 164:20, 203:14</p> <p>relies [1] - 177:4</p> <p>relievers [1] - 185:8</p> <p>rely [13] - 93:6, 121:12, 121:16, 125:14, 125:15, 159:1, 159:2, 164:22, 164:23, 164:25, 167:1, 242:16, 243:1</p> <p>relying [3] - 38:25, 145:18, 178:22</p> <p>remain [3] - 26:12, 26:14, 28:21</p> <p>remained [1] - 138:21</p> <p>remaining [1] - 177:18</p>	<p>remarkable [1] - 217:18</p> <p>remarkably [1] - 195:22</p> <p>remember [35] - 21:8, 21:11, 21:21, 22:2, 22:3, 23:23, 25:11, 26:3, 28:10, 37:1, 37:16, 39:23, 41:6, 41:19, 67:24, 71:25, 79:18, 84:5, 84:9, 86:1, 87:25, 88:13, 88:18, 91:2, 91:9, 139:7, 139:9, 160:25, 190:16, 191:18, 191:24, 200:25, 219:12, 223:7, 245:1</p> <p>remind [2] - 74:8, 213:17</p> <p>reminded [1] - 213:14</p> <p>remote [2] - 107:11, 107:23</p> <p>renew [2] - 45:15, 51:16</p> <p>repeat [4] - 66:14, 72:1, 76:4, 102:24</p> <p>repeatedly [1] - 244:6</p> <p>replace [1] - 174:5</p> <p>report [100] - 9:5, 9:9, 9:12, 13:20, 25:20, 28:14, 28:16, 47:23, 73:22, 87:7, 87:25, 88:3, 116:7, 116:9, 116:11, 116:15, 126:17, 128:4, 129:5, 132:12, 132:15, 134:23, 135:14, 139:6, 139:12, 139:13, 139:17, 139:18, 139:21, 140:4, 140:5, 140:9, 142:13, 148:19, 150:11, 150:12, 150:13, 150:18, 152:2, 152:7, 152:9, 158:19, 163:3, 174:23, 175:8, 175:21, 176:1, 176:5, 176:12, 177:3, 178:9, 178:11, 179:14, 180:7, 184:7, 184:23, 185:9, 185:10, 185:23, 185:24, 186:1, 186:7, 187:8, 187:13, 187:18, 187:20, 188:14,</p>	<p>188:21, 188:24, 189:3, 189:8, 189:19, 190:5, 190:8, 190:24, 194:15, 194:22, 194:23, 199:4, 199:10, 200:1, 201:23, 203:15, 205:18, 205:24, 207:8, 218:10, 218:12, 218:13, 223:10, 224:12, 224:25, 225:4, 225:9, 225:11, 225:16, 236:6, 236:13, 237:24</p> <p>Report [2] - 176:23, 186:2</p> <p>report's [1] - 225:9</p> <p>reported [7] - 152:7, 159:6, 166:22, 189:19, 201:24, 202:3, 246:9</p> <p>Reporter [6] - 6:17, 6:18, 246:3, 246:12</p> <p>reporter [1] - 121:4</p> <p>REPORTER [7] - 98:24, 99:2, 105:3, 105:15, 115:18, 115:20, 120:25</p> <p>reporters [2] - 36:5, 36:12</p> <p>Reporting [1] - 88:11</p> <p>reporting [7] - 26:1, 26:2, 26:23, 28:11, 47:15, 145:21, 150:19</p> <p>Reports [6] - 49:2, 53:1, 53:5, 54:13, 55:4, 56:14</p> <p>reports [14] - 13:23, 14:13, 112:15, 118:6, 125:12, 129:11, 134:17, 153:18, 170:5, 175:6, 179:8, 181:25, 189:22, 221:2</p> <p>represent [2] - 43:3, 50:4</p> <p>representation [2] - 244:6, 244:9</p> <p>representative [1] - 231:11</p> <p>representatives [3] - 12:4, 64:16, 86:8</p> <p>represented [3] - 19:20, 35:17, 61:14</p> <p>representing [1] - 205:22</p>	<p>request [2] - 45:21, 67:4</p> <p>requesting [1] - 18:10</p> <p>required [5] - 40:1, 43:12, 47:16, 94:23, 159:24</p> <p>requirement [2] - 72:22, 90:22</p> <p>requirements [3] - 44:14, 48:1, 60:14</p> <p>rescheduling [1] - 213:18</p> <p>research [32] - 100:13, 101:16, 104:12, 106:16, 107:7, 107:8, 109:13, 109:16, 111:10, 113:10, 115:5, 116:7, 119:25, 121:13, 121:15, 125:18, 146:4, 148:5, 148:9, 148:10, 153:3, 154:18, 181:7, 181:13, 204:8, 218:6, 220:2, 225:17, 228:24, 230:15, 231:14, 235:22</p> <p>Research [2] - 107:1, 108:22</p> <p>researched [1] - 141:25</p> <p>researchers [1] - 113:6</p> <p>researching [1] - 154:16</p> <p>residency [1] - 104:22</p> <p>resident [2] - 104:2, 104:4</p> <p>residents [3] - 101:6, 183:2, 183:21</p> <p>residues [1] - 137:8</p> <p>resolution [1] - 71:11</p> <p>resolve [1] - 72:4</p> <p>Resources [1] - 148:22</p> <p>respect [5] - 16:6, 41:23, 51:14, 56:13, 239:11</p> <p>respectfully [1] - 58:2</p> <p>respective [1] - 180:21</p> <p>respiration [1] - 189:17</p> <p>respondent [1] - 42:24</p> <p>respondent's [1] - 94:25</p> <p>Respondent's [1] -</p>
---	--	--	--	---

<p>43:14</p> <p>responders [2] - 179:25, 220:2</p> <p>response [4] - 38:8, 39:20, 76:10, 239:20</p> <p>responses [1] - 60:4</p> <p>responsibility [1] - 87:2</p> <p>responsible [7] - 100:2, 100:15, 139:2, 189:6, 196:12, 202:24, 231:3</p> <p>responsive [2] - 80:23, 83:1</p> <p>rest [3] - 37:18, 39:2, 93:20</p> <p>restrict [1] - 183:20</p> <p>result [4] - 15:20, 17:15, 21:23, 166:14</p> <p>resulted [2] - 22:11, 94:3</p> <p>results [5] - 144:22, 146:3, 149:12, 181:4, 192:22</p> <p>retail [14] - 34:10, 34:11, 34:25, 35:1, 79:17, 80:2, 81:4, 81:7, 81:9, 82:23, 229:25, 231:1, 231:3</p> <p>retailer [4] - 238:8, 238:18, 238:25</p> <p>retailers [2] - 232:2, 237:16</p> <p>retained [1] - 114:2</p> <p>retired [2] - 62:18, 74:12</p> <p>returned [1] - 197:14</p> <p>revealed [1] - 220:20</p> <p>review [27] - 14:19, 19:19, 30:3, 42:8, 82:15, 119:23, 124:19, 125:7, 125:11, 128:1, 128:10, 130:2, 130:18, 130:19, 134:25, 136:1, 138:12, 142:3, 144:25, 145:14, 145:15, 146:4, 165:2, 165:13, 173:11, 177:14, 180:6</p> <p>Review [1] - 233:11</p> <p>reviewed [13] - 11:5, 11:8, 45:19, 113:20, 120:9, 121:6, 124:14, 125:23, 132:21, 157:23, 167:22, 177:12,</p>	<p>241:12</p> <p>reviewing [10] - 14:6, 21:1, 21:9, 55:7, 69:21, 69:24, 163:7, 164:21, 233:16, 241:21</p> <p>reviews [4] - 12:6, 29:8, 29:15, 29:25</p> <p>revision [2] - 49:14, 100:21</p> <p>revoke [2] - 64:17, 86:9</p> <p>revoked [3] - 26:15, 26:18, 26:20</p> <p>Reynolds [5] - 85:12, 94:20, 194:18, 199:6, 205:17</p> <p>Rice [5] - 2:9, 3:14, 4:3, 4:5, 4:8</p> <p>Richmond [1] - 8:6</p> <p>right-hand [7] - 171:19, 187:19, 193:24, 211:8, 218:17, 238:12, 238:22</p> <p>rise [6] - 135:5, 136:13, 138:17, 139:1, 139:10, 194:13</p> <p>risk [12] - 98:13, 99:16, 99:18, 109:24, 110:14, 110:15, 111:12, 112:9, 144:16, 162:19, 162:23</p> <p>risks [3] - 162:14, 162:17, 162:18</p> <p>Ritchie [5] - 8:19, 17:24, 18:23, 24:22, 33:18</p> <p>RMR [2] - 6:17, 6:18</p> <p>road [1] - 108:17</p> <p>ROBERT [1] - 6:11</p> <p>ROBERTSON [1] - 3:6</p> <p>role [20] - 109:25, 141:11, 141:23, 144:18, 145:8, 148:13, 153:5, 153:15, 153:21, 228:18, 229:24, 231:23, 232:7, 236:6, 237:18, 238:23, 239:7, 239:15, 239:25, 240:13</p> <p>roughly [2] - 134:7, 139:24</p> <p>round [1] - 93:16</p> <p>rounding [1] - 116:21</p> <p>routes [1] - 146:25</p>	<p>row [2] - 207:7, 215:15</p> <p>RPR [1] - 6:18</p> <p>RPR-RMR-CRR-FCRR [1] - 6:18</p> <p>Ruby [5] - 4:17, 205:13, 205:21, 212:22, 214:14</p> <p>RUBY [8] - 4:17, 205:14, 205:20, 209:4, 212:23, 214:12, 214:15, 226:9</p> <p>Rule [3] - 59:19, 60:14, 60:24</p> <p>rule [3] - 43:14, 95:16, 240:9</p> <p>ruled [1] - 65:19</p> <p>rulemaking [3] - 94:24, 95:8, 95:11</p> <p>rules [2] - 95:10, 187:6</p> <p>ruling [1] - 58:3</p> <p>run [8] - 38:22, 39:7, 39:16, 39:22, 91:19, 91:23, 107:16, 117:16</p> <p>running [1] - 238:16</p> <p>rural [15] - 103:12, 104:24, 107:23, 111:1, 111:7, 112:4, 144:11, 215:6, 215:8, 215:14, 215:25, 216:4, 216:5, 216:7, 218:6</p> <p>rustling [1] - 66:25</p>	<p>216:16</p> <p>SC [3] - 3:15, 4:4, 4:9</p> <p>scale [2] - 62:3, 94:4</p> <p>scared [1] - 221:25</p> <p>scatter [1] - 215:16</p> <p>scene [3] - 123:1, 123:8, 167:2</p> <p>Schedule [1] - 151:18</p> <p>Schmidt [14] - 38:1, 39:15, 46:5, 46:19, 57:10, 63:23, 66:5, 66:11, 66:15, 77:11, 77:14, 83:11, 83:24, 84:8</p> <p>SCHMIDT [53] - 5:9, 37:2, 37:21, 38:9, 38:16, 43:24, 45:4, 45:15, 46:8, 48:5, 53:10, 54:5, 54:16, 55:6, 55:20, 56:17, 57:6, 57:11, 59:15, 60:4, 65:15, 65:18, 67:7, 67:13, 68:13, 68:18, 69:8, 70:17, 71:12, 71:20, 74:5, 74:23, 75:11, 75:21, 77:15, 83:9, 83:13, 83:18, 85:11, 85:14, 85:18, 85:20, 91:14, 91:18, 94:19, 94:21, 95:19, 96:4, 96:10, 243:15, 243:19, 244:5, 245:4</p> <p>School [9] - 97:24, 98:4, 101:9, 101:10, 101:11, 104:6, 104:12, 106:21, 107:5</p> <p>school [1] - 103:22</p> <p>schools [2] - 103:22, 103:23</p> <p>science [1] - 213:2</p> <p>Science [3] - 191:10, 191:13, 191:14</p> <p>sciences [1] - 103:18</p> <p>scientist [1] - 106:16</p> <p>scientists [1] - 192:11</p> <p>scope [10] - 45:5, 45:18, 46:13, 77:2, 77:3, 77:13, 115:23, 115:25, 211:23, 213:8</p> <p>screen [8] - 79:4, 83:23, 85:18, 159:21, 159:24, 218:17, 228:11, 238:2</p> <p>screwing [1] - 19:1</p> <p>script [1] - 187:9</p> <p>scroll [1] - 91:14</p>	<p>seat [2] - 97:14, 227:19</p> <p>second [20] - 14:10, 34:5, 42:21, 46:3, 49:18, 49:20, 65:10, 69:15, 77:20, 91:16, 131:6, 192:18, 214:23, 214:25, 215:9, 217:6, 217:7, 240:9, 243:22</p> <p>seconds [1] - 96:17</p> <p>section [11] - 9:16, 28:13, 33:20, 159:7, 160:7, 176:8, 176:18, 188:1, 192:19, 192:22, 220:16</p> <p>Section [5] - 29:3, 47:16, 48:2, 180:12, 187:15</p> <p>security [1] - 8:1</p> <p>See [2] - 244:25, 245:5</p> <p>see [155] - 11:6, 11:11, 11:22, 12:12, 14:21, 14:22, 17:7, 18:24, 18:25, 25:23, 26:16, 30:17, 34:2, 34:13, 35:2, 39:4, 39:6, 39:18, 43:5, 51:4, 52:17, 56:2, 64:5, 70:12, 70:21, 75:22, 85:24, 86:13, 87:8, 87:21, 88:6, 91:11, 91:19, 92:4, 92:8, 92:23, 93:18, 94:22, 95:1, 95:13, 96:21, 101:25, 104:16, 105:19, 107:20, 112:17, 115:11, 126:1, 128:17, 128:18, 130:9, 132:10, 132:18, 132:25, 136:3, 136:4, 136:12, 136:13, 137:21, 138:17, 138:18, 138:23, 138:24, 144:14, 147:15, 155:10, 155:11, 165:15, 170:1, 171:21, 171:25, 172:7, 172:8, 172:18, 173:16, 173:18, 173:21, 176:9, 176:20, 178:11, 180:1, 180:11, 180:24, 182:25, 183:5, 183:6, 184:5, 184:11, 184:17,</p>
S				
<p>sAyme [1] - 246:11</p> <p>sLisa [1] - 246:11</p> <p>safe [1] - 98:2</p> <p>sale [6] - 25:20, 26:6, 26:7, 26:25, 221:10, 240:19</p> <p>sales [12] - 10:15, 12:9, 12:11, 21:10, 25:11, 26:25, 27:14, 27:17, 27:19, 28:6, 30:14</p> <p>SALGADO [1] - 4:15</p> <p>samples [1] - 123:2</p> <p>San [2] - 2:5, 2:17</p> <p>satisfied [2] - 55:4, 56:15</p> <p>satisfy [1] - 57:22</p> <p>save [2] - 64:8, 103:2</p> <p>saw [10] - 53:14, 54:7, 62:3, 68:15, 117:23, 130:15, 131:20, 139:1, 216:14,</p>				

<p>185:4, 185:13, 185:14, 187:15, 187:16, 187:23, 188:8, 188:9, 188:17, 191:8, 191:11, 192:5, 192:6, 192:17, 192:19, 193:2, 193:6, 193:7, 193:8, 193:21, 193:25, 194:4, 194:13, 195:3, 195:4, 195:6, 195:16, 195:24, 195:25, 197:6, 197:18, 197:19, 199:20, 199:23, 200:10, 201:7, 201:11, 203:19, 204:7, 204:14, 204:21, 204:22, 204:23, 206:20, 207:5, 207:19, 208:3, 208:11, 208:23, 210:6, 210:23, 211:8, 215:1, 215:4, 215:6, 216:13, 217:3, 217:12, 217:14, 217:23, 218:13, 220:11, 224:17, 223:5, 243:10, 243:13 seeing [4] - 127:20, 150:23, 213:14, 243:5 seem [2] - 22:2, 224:3 select [2] - 64:13, 161:3 selection [1] - 232:21 Selection [1] - 233:5 sell [4] - 203:1, 203:4, 203:7, 203:10 seminal [1] - 231:17 Senate [1] - 90:19 send [1] - 124:24 Senior [1] - 7:2 senior [4] - 90:14, 109:9, 127:5, 229:6 SENIOR [1] - 1:17 senior-level [1] - 229:6 Sensabaugh [1] - 5:14 sense [1] - 8:15 sensitive [4] - 168:3, 168:10, 168:20, 171:9 sent [15] - 47:8, 49:6, 49:8, 49:10, 52:25, 53:3, 123:3, 123:15, 123:16, 123:18,</p>	<p>123:21, 123:23, 124:22, 124:23, 241:17 sentence [21] - 17:1, 25:16, 26:9, 29:4, 29:5, 34:8, 40:13, 40:19, 41:8, 47:19, 72:16, 72:18, 92:18, 94:18, 94:22, 184:3, 188:2, 210:6, 217:23, 217:24, 217:25 sentences [1] - 147:12 separate [6] - 98:9, 100:21, 123:24, 124:9, 224:18, 225:15 September [6] - 32:20, 33:6, 33:12, 47:6, 71:1, 155:9 sequelae [1] - 214:3 seriously [3] - 84:23, 93:11, 93:21 serve [3] - 233:1, 233:9, 233:11 served [5] - 99:5, 99:8, 232:21, 233:2, 239:10 service [1] - 228:24 services [2] - 241:18, 241:19 sessions [1] - 8:11 set [9] - 41:6, 48:1, 82:10, 117:13, 143:22, 185:21, 185:25, 235:11, 237:9 sets [2] - 151:5, 216:19 Setting [1] - 182:24 settled [1] - 183:20 settlement [1] - 72:4 Settlement [11] - 24:7, 24:11, 24:17, 25:2, 26:22, 29:11, 32:17, 32:22, 45:2, 47:2, 86:21 setup [1] - 75:1 several [8] - 19:21, 180:17, 197:17, 224:13, 233:12, 234:15, 236:1, 244:23 shall [5] - 25:18, 26:11, 26:14, 30:10, 72:19 SHANNON [1] - 6:3 shape [1] - 210:11 sharply [1] - 139:24 shift [1] - 109:7</p>	<p>ship [5] - 23:1, 43:23, 44:6, 44:14, 44:16 shipping [1] - 44:11 shoes [1] - 238:16 shopping [4] - 146:11, 146:12, 146:19 short [4] - 119:1, 156:21, 198:8, 199:11 shortcut [1] - 225:5 show [22] - 18:18, 24:25, 37:18, 63:19, 80:4, 116:18, 131:17, 135:4, 141:20, 142:6, 142:14, 143:7, 150:20, 169:9, 173:24, 179:18, 188:20, 188:24, 195:20, 198:3, 220:16, 225:3 Show [11] - 11:22, 11:23, 17:17, 22:7, 62:24, 63:9, 63:21, 65:6, 71:11, 72:4, 85:21 showed [15] - 37:14, 38:13, 38:16, 58:16, 61:7, 79:9, 80:10, 85:7, 86:23, 99:7, 130:6, 145:25, 156:21, 179:14, 224:24 showing [6] - 36:24, 37:10, 79:15, 102:25, 109:24, 126:17 shown [17] - 9:1, 63:23, 73:22, 94:15, 94:16, 94:17, 117:8, 158:8, 158:19, 159:10, 192:21, 196:6, 209:17, 215:24, 218:2, 220:13, 225:13 shows [13] - 42:8, 127:7, 128:8, 129:8, 135:4, 138:6, 189:7, 194:24, 198:18, 201:6, 217:9, 238:5, 238:23 shut [2] - 23:23, 24:2 shutdown [5] - 22:11, 22:15, 22:17, 23:25, 24:4 sic [4] - 11:4, 34:10, 51:22, 131:22 side [12] - 55:10, 66:25, 81:11, 129:6, 176:2, 176:4,</p>	<p>180:11, 193:24, 196:25, 238:6, 238:12, 238:22 sides [1] - 67:8 signed [3] - 62:25, 63:5, 63:9 significant [7] - 145:24, 148:14, 151:20, 161:2, 161:5, 200:22, 217:14 significantly [3] - 134:13, 138:7, 183:14 signs [1] - 65:1 Silicon [3] - 230:17, 230:24, 234:16 similar [6] - 142:2, 149:18, 149:22, 153:2, 174:22, 196:16 Simply [1] - 238:25 simply [8] - 21:12, 42:10, 42:19, 79:4, 82:18, 214:16, 215:18, 235:14 Singer [3] - 66:19, 78:11, 80:24 singer [17] - 36:14, 45:20, 46:16, 51:4, 51:18, 53:16, 54:19, 57:20, 58:4, 59:17, 60:5, 67:16, 68:24, 69:14, 70:22, 78:15, 82:24 SINGER [84] - 4:5, 36:15, 36:20, 37:7, 37:20, 37:22, 37:25, 38:13, 38:19, 44:9, 45:11, 45:21, 46:17, 46:23, 48:11, 48:13, 48:16, 48:24, 51:6, 51:7, 51:20, 51:24, 53:17, 53:20, 53:21, 54:9, 54:23, 54:25, 55:13, 56:4, 56:9, 56:19, 57:2, 57:16, 58:5, 58:8, 59:12, 59:18, 61:2, 61:4, 61:5, 63:17, 65:24, 65:25, 66:22, 67:17, 67:24, 68:4, 68:6, 68:17, 68:25, 69:2, 69:15, 69:17, 70:6, 70:8, 70:23, 71:23, 71:24, 74:7, 74:14, 74:17, 75:4, 75:16, 75:17, 76:6, 76:7, 77:8, 78:18, 78:21, 78:22, 79:25, 80:25,</p>	<p>81:2, 82:25, 83:4, 83:11, 83:15, 83:20, 83:21, 83:25, 84:2, 85:9, 96:2 single [7] - 77:18, 81:1, 91:20, 91:22, 102:15, 184:21, 185:11 SIR [1] - 96:8 sit [3] - 167:4, 186:25, 243:18 site [1] - 30:7 sites [1] - 10:20 situation [2] - 160:23, 244:16 six [3] - 11:9, 103:17, 181:19 six-year [1] - 103:17 Skecher [1] - 238:17 skilled [1] - 148:16 skip [1] - 43:10 skipped [1] - 50:13 Slide [11] - 79:15, 79:16, 122:6, 126:10, 129:2, 129:5, 131:12, 135:7, 137:15, 141:18 slide [34] - 50:21, 50:23, 51:9, 51:15, 60:20, 80:13, 89:3, 89:9, 110:17, 117:8, 126:17, 128:6, 128:10, 129:8, 130:15, 131:12, 135:23, 136:9, 136:10, 136:21, 137:19, 137:25, 138:11, 138:14, 140:17, 149:1, 152:3, 152:4, 199:8, 228:7, 228:10, 228:16, 232:10, 232:13 slides [10] - 50:14, 58:17, 60:5, 60:6, 61:7, 101:19, 102:4, 102:5, 102:15, 204:23 Slow [1] - 105:6 slow [4] - 83:18, 98:24, 105:16, 112:20 slowly [1] - 119:4 small [23] - 18:22, 84:4, 84:20, 92:20, 93:1, 93:13, 94:11, 103:12, 128:16, 130:23, 137:14, 166:2, 166:9, 176:2,</p>
---	--	---	--	---

176:4, 180:10, 181:11, 181:18, 187:19, 195:14, 204:25 smart [1] - 174:13 smiled [1] - 86:16 SMITH [1] - 97:12 Smith [25] - 6:4, 6:11, 97:5, 97:9, 97:21, 97:23, 101:19, 103:1, 114:7, 114:11, 114:17, 119:3, 119:16, 119:20, 122:9, 135:10, 140:1, 153:14, 155:3, 155:8, 182:9, 205:21, 224:8, 226:8, 226:10 Smith's [4] - 178:9, 224:12, 225:4, 225:21 smoke [1] - 79:4 smooth [3] - 195:23, 196:5, 218:1 snapshot [1] - 30:1 Snow [1] - 98:22 societies [1] - 108:9 Society [1] - 108:14 softer [1] - 21:24 sold [2] - 201:18, 231:5 solely [1] - 60:6 someone [6] - 28:22, 36:17, 77:16, 98:11, 112:18, 122:18 sometime [1] - 47:3 sometimes [7] - 112:18, 116:1, 116:21, 159:17, 214:1, 242:2, 242:21 Somewhat [1] - 22:14 somewhere [2] - 157:21, 158:4 soon [1] - 124:8 Sorry [3] - 14:1, 99:2, 192:23 sorry [43] - 14:2, 15:21, 19:4, 32:9, 34:20, 37:8, 39:5, 45:11, 46:25, 47:7, 48:13, 50:13, 50:14, 51:22, 52:5, 57:16, 59:11, 61:20, 67:24, 69:18, 76:4, 79:16, 91:7, 97:2, 101:4, 105:3, 105:15, 115:18, 115:19, 120:25, 142:24, 144:23, 172:2,	172:3, 187:25, 192:22, 193:10, 193:12, 220:24, 236:24, 241:5, 243:16 SORS [3] - 88:8, 88:9, 88:10 sort [6] - 32:4, 103:18, 108:25, 109:6, 154:5, 216:8 sorts [2] - 237:19, 240:17 sound [2] - 93:24, 122:2 sounding [1] - 104:14 sounds [1] - 105:11 Source [1] - 231:21 source [12] - 60:9, 60:23, 61:8, 95:15, 117:8, 124:25, 134:24, 135:1, 155:16, 155:19, 155:21, 223:13 sources [5] - 17:6, 111:17, 120:5, 149:17, 185:2 South [1] - 2:13 Southern [1] - 7:2 SOUTHERN [1] - 1:1 southern [2] - 110:21, 111:21 Southwood [1] - 95:16 space [1] - 236:3 spatial [1] - 218:2 speaker [7] - 50:17, 50:19, 50:23, 51:1, 51:8, 51:10, 51:12 speaking [2] - 77:22, 118:17 speaks [1] - 213:6 special [2] - 52:15, 210:19 specialist [1] - 213:2 specialize [1] - 99:24 specialized [2] - 122:25, 125:9 specialties [1] - 99:24 specialty [8] - 98:4, 99:21, 99:25, 100:4, 229:8, 229:17, 229:18, 230:2 specific [32] - 8:8, 21:2, 28:6, 71:17, 76:19, 76:22, 110:9, 112:13, 113:23, 118:16, 129:24, 130:22, 133:6, 133:8, 133:10, 136:7, 139:11,	156:14, 157:12, 162:15, 163:25, 164:1, 168:18, 169:4, 180:8, 210:16, 218:2, 221:14, 222:5, 241:1, 241:7 specifically [14] - 23:2, 60:14, 82:12, 88:15, 115:4, 116:1, 124:13, 128:8, 130:7, 130:18, 145:5, 177:1, 199:5, 222:22 specifics [3] - 71:5, 115:15, 115:16 speculative [1] - 63:11 spent [4] - 83:5, 100:6, 106:22, 166:25 sponsored [1] - 32:18 spot [2] - 217:12, 217:15 Spotlight [1] - 223:10 spots [1] - 217:13 spread [1] - 218:3 Square [2] - 6:5, 6:12 stable [3] - 131:17, 131:25, 195:1 staff [4] - 51:13, 63:1, 63:8, 88:9 stairs [1] - 112:19 stand [4] - 42:23, 60:2, 97:5, 119:12 standard [11] - 120:2, 120:17, 124:24, 125:20, 129:17, 129:18, 129:23, 129:25, 143:25, 239:20 STANNER [1] - 5:10 star [2] - 140:21, 140:23 starred [1] - 140:20 stars [1] - 154:5 start [19] - 10:4, 19:2, 24:24, 36:17, 37:24, 84:18, 85:17, 96:12, 102:4, 107:7, 107:14, 115:20, 121:19, 138:24, 156:8, 217:13, 217:17, 227:8, 239:25 started [13] - 41:4, 107:8, 107:18, 111:3, 115:13, 117:11, 117:21, 128:17, 131:22, 131:23, 136:3,	233:20, 235:3 starting [8] - 56:11, 127:15, 131:9, 133:3, 136:7, 211:11, 215:17, 217:22 starts [2] - 12:3, 217:23 State [27] - 23:1, 38:25, 104:24, 113:2, 114:9, 114:13, 117:10, 118:1, 121:25, 122:9, 122:17, 123:20, 132:20, 136:6, 143:11, 145:1, 145:8, 146:6, 149:13, 150:6, 150:16, 152:25, 156:11, 157:2, 223:10, 234:2, 234:9 state [54] - 37:6, 42:25, 57:23, 77:10, 77:18, 78:12, 97:8, 110:6, 113:9, 113:18, 113:19, 116:5, 119:23, 121:16, 121:18, 121:19, 121:20, 123:24, 124:1, 127:14, 128:16, 128:19, 128:25, 129:19, 129:22, 130:21, 131:2, 131:7, 131:8, 132:3, 132:4, 132:8, 142:10, 142:22, 143:12, 143:21, 145:3, 145:6, 145:16, 147:21, 147:22, 149:11, 157:25, 183:2, 183:21, 185:20, 197:25, 198:13, 198:15, 198:16, 205:1, 227:14, 228:25, 241:7 statement [25] - 74:25, 75:5, 75:7, 75:12, 75:15, 75:19, 75:24, 76:2, 76:8, 76:19, 76:23, 77:10, 78:16, 79:6, 80:5, 85:3, 85:4, 85:6, 88:15, 92:11, 92:25, 147:19, 184:14, 184:17, 212:24 statements [9] - 76:14, 76:15, 76:22, 76:24, 77:4, 77:5,	84:11, 85:7, 94:2 STATES [2] - 1:1, 1:17 States [18] - 7:2, 47:9, 55:14, 89:20, 89:23, 90:4, 90:7, 90:18, 95:12, 104:3, 104:4, 104:5, 104:8, 180:18, 191:6, 192:25, 197:9, 220:19 states [9] - 39:1, 62:7, 113:14, 118:4, 122:11, 124:22, 128:13, 129:16, 144:11 statewide [3] - 122:10, 130:18, 130:19 stating [1] - 89:12 station [1] - 107:17 statistic [2] - 169:13, 188:11 Statistics [11] - 108:13, 117:10, 117:15, 117:17, 118:3, 123:17, 124:12, 127:6, 143:16, 149:25, 199:15 statistics [8] - 113:15, 118:2, 122:2, 124:11, 124:25, 125:2, 126:2, 150:23 status [1] - 101:10 STATUS [1] - 1:17 Status [1] - 7:2 stenography [1] - 6:19 step [5] - 79:5, 119:16, 145:20, 182:9, 243:17 Stephen [1] - 97:9 STEPHEN [1] - 97:12 stepped [1] - 97:1 steps [3] - 17:14, 17:20, 20:7 Stern [3] - 232:16, 232:18, 233:4 Steve [2] - 9:14, 205:21 STEVEN [1] - 4:17 stick [2] - 173:14, 196:24 sticking [1] - 107:12 still [23] - 27:16, 27:19, 28:7, 28:12, 28:14, 33:9, 33:10, 54:6, 68:11, 69:6, 97:17, 112:20, 131:8, 141:24, 142:11, 144:23, 154:16, 154:18,
---	--	--	--	--

<p>157:9, 212:25 stood [1] - 77:12 stop [3] - 41:13, 85:3, 105:5 stopped [6] - 23:20, 40:4, 91:10, 91:11, 93:17, 106:11 stopping [3] - 182:5, 242:6, 242:9 stops [1] - 39:8 stories [2] - 170:9, 174:14 straightforward [1] - 19:9 Strategic [1] - 232:1 strategic [3] - 232:2, 242:19, 242:20 strategies [8] - 106:7, 229:25, 230:5, 232:4, 235:11, 237:9, 242:18, 243:6 Strategies [1] - 231:20 strategy [4] - 229:19, 230:10, 231:24, 242:23 street [3] - 177:25, 184:8, 184:10 Street [15] - 2:7, 2:10, 2:13, 3:5, 3:7, 3:10, 3:12, 4:6, 4:13, 4:15, 4:18, 5:5, 5:12, 6:6, 6:13 stressed [2] - 34:8, 34:23 strongly [1] - 197:16 students [3] - 98:21, 127:5, 229:6 studied [7] - 99:6, 99:10, 107:22, 183:24, 205:6, 231:23, 233:18 studies [11] - 98:11, 98:12, 106:4, 107:2, 113:1, 113:5, 121:8, 142:8, 153:3, 163:22, 218:7 study [47] - 98:18, 100:9, 103:25, 105:24, 106:1, 109:21, 110:20, 111:20, 115:8, 124:9, 142:13, 142:18, 142:20, 142:21, 143:8, 145:7, 145:20, 147:11, 147:25, 148:1, 148:8, 148:12, 148:18, 148:21, 149:7, 149:10, 149:13,</p>	<p>149:16, 149:21, 150:13, 150:22, 151:9, 152:14, 152:22, 153:1, 155:16, 183:2, 183:7, 185:2, 185:15, 185:16, 185:19, 185:20, 192:14, 220:20, 221:13 studying [3] - 110:18, 111:2, 235:18 stuff [3] - 115:12, 198:7, 203:9 stymies [1] - 55:20 sub [3] - 210:19, 211:5, 222:18 subject [6] - 22:23, 23:21, 114:8, 114:12, 175:21, 175:22 submit [1] - 168:23 submitted [3] - 9:5, 13:21, 60:1 subparagraph [1] - 30:9 subpart [1] - 25:5 subsection [1] - 100:8 subsequently [1] - 17:18 subset [2] - 156:20, 156:23 subspecialty [1] - 233:13 substance [17] - 13:22, 25:20, 26:5, 26:24, 66:17, 69:5, 88:17, 106:23, 106:24, 111:14, 112:3, 112:8, 146:17, 146:23, 186:8, 186:12, 186:20 Substances [2] - 92:22, 151:15 substances [16] - 23:1, 30:13, 30:15, 47:10, 64:13, 64:15, 64:21, 70:3, 72:21, 83:7, 84:4, 93:23, 94:5, 147:2, 151:18, 201:2 substantial [1] - 147:14 substantive [1] - 169:20 substitute [2] - 171:10, 184:9 successfully [1] - 60:17</p>	<p>successive [1] - 146:16 succinct [1] - 214:19 suddenly [1] - 198:19 sufficient [4] - 55:4, 56:14, 56:15, 73:24 sufficiently [1] - 223:15 suggest [1] - 211:17 suggested [4] - 16:4, 18:9, 19:11, 19:16 suggesting [2] - 12:23, 18:10 suggestions [2] - 17:20, 30:11 suggests [8] - 176:19, 197:16, 198:18, 210:4, 212:8, 213:21, 218:23, 219:7 Suite [9] - 2:4, 2:7, 2:10, 2:13, 2:16, 3:17, 4:6, 6:5, 6:12 sum [1] - 195:21 summarized [2] - 164:17, 167:21 summarizes [1] - 242:22 summary [4] - 138:3, 152:9, 193:4, 193:6 Summary [1] - 150:10 supervision [3] - 75:6, 76:9, 76:25 supplement [1] - 43:1 supplemental [1] - 243:20 supply [5] - 17:6, 40:24, 99:5, 233:1, 236:2 supporting [1] - 89:3 suppose [1] - 244:25 supposed [1] - 86:6 suppress [1] - 189:17 suppressed [1] - 118:14 Supreme [3] - 95:9, 95:12, 109:1 surge [1] - 197:11 surgeons [1] - 203:8 surprise [2] - 36:19, 154:4 surprised [3] - 138:20, 183:18, 185:5 surprising [1] - 154:3 survey [10] - 61:21, 62:10, 88:21, 88:22, 88:23, 88:25, 89:4, 89:5 suspect [1] - 239:18 suspected [1] - 23:11</p>	<p>suspicious [20] - 13:23, 14:16, 14:18, 15:8, 17:23, 27:21, 28:14, 33:21, 34:2, 43:23, 47:15, 47:24, 50:21, 50:24, 51:15, 64:19, 72:13, 72:17, 72:20, 86:11 Suspicious [6] - 62:13, 62:19, 63:5, 65:12, 73:17, 88:11 sustain [8] - 51:17, 53:18, 54:18, 54:21, 57:19, 65:22, 225:7, 226:1 sustained [3] - 37:5, 54:8, 74:6 SUZANNE [1] - 4:15 switch [3] - 36:4, 214:7, 226:20 SWORN [2] - 97:12, 227:18 system [35] - 38:22, 38:24, 41:5, 41:9, 41:10, 41:11, 41:12, 41:13, 41:14, 41:16, 62:22, 62:23, 68:10, 68:11, 69:5, 69:6, 70:2, 72:19, 73:1, 73:11, 93:6, 110:15, 117:14, 126:22, 145:22, 157:10, 188:15, 206:10, 207:1, 207:10, 207:24, 208:7, 208:16, 208:25 System [5] - 62:14, 62:20, 63:6, 65:13, 88:11 systems [7] - 17:18, 20:25, 69:21, 69:24, 100:12, 206:2, 206:15</p>	<p>technically [3] - 125:6, 231:22, 233:20 technique [1] - 130:1 Technology [1] - 229:7 technology [3] - 230:5, 230:6, 232:7 technology-driven [1] - 230:6 techs [1] - 59:9 TEMITOPE [1] - 4:8 ten [4] - 96:17, 152:22, 152:25, 182:7 tender [1] - 114:6 Tenth [1] - 5:12 tenure [9] - 7:22, 44:20, 45:24, 46:20, 58:23, 62:18, 72:23, 75:9, 89:18 term [5] - 26:18, 26:20, 130:4, 131:16, 197:5 terminate [1] - 29:1 terminated [2] - 26:14, 28:22 terms [7] - 25:9, 77:19, 117:1, 170:21, 210:10, 231:4, 240:5 Terry [5] - 53:4, 53:11, 53:24, 54:1, 54:2 test [3] - 36:16, 39:5, 175:1 tested [1] - 111:11 testified [22] - 32:11, 41:2, 41:24, 50:9, 52:20, 56:23, 61:8, 61:17, 61:22, 62:12, 65:10, 158:19, 183:8, 183:24, 186:7, 191:19, 198:8, 199:11, 225:1, 225:12, 225:18, 226:2 testify [10] - 64:9, 65:6, 70:19, 75:2, 77:9, 86:5, 86:6, 86:7, 190:20, 216:20 testifying [6] - 54:5, 66:1, 71:14, 77:17, 205:23, 215:20 testimony [43] - 16:19, 16:20, 25:6, 25:12, 32:15, 36:24, 37:10, 39:11, 40:9, 41:8, 46:9, 46:12, 46:14, 55:15, 57:3, 61:10, 61:14, 64:2, 64:6, 65:5, 66:6, 68:19, 85:25, 86:3, 91:2,</p>
---	--	--	--	---

T

tabulate [1] - 124:10
tagged [1] - 209:14
talks [3] - 28:14, 214:1, 214:6
tallying [1] - 153:6
tasked [1] - 115:5
taught [1] - 229:9
teach [4] - 229:4, 229:5, 229:6, 229:8
teaching [2] - 98:21, 228:24
tech [1] - 237:8
technical [2] - 103:20, 112:15

<p>91:10, 96:20, 101:21, 131:15, 155:18, 156:18, 165:17, 186:6, 201:17, 218:4, 221:18, 224:21, 224:24, 225:22, 225:24, 226:24, 228:8, 243:22 testing [2] - 170:23, 185:6 Texas [1] - 32:19 text [1] - 194:23 textbooks [1] - 237:25 THE [202] - 1:1, 1:1, 1:4, 1:17, 7:5, 7:10, 7:14, 7:15, 8:23, 8:24, 13:24, 14:2, 15:15, 19:5, 19:6, 24:20, 32:7, 36:2, 36:4, 36:8, 36:11, 36:14, 37:5, 38:15, 38:18, 44:3, 44:5, 45:7, 45:9, 45:14, 45:20, 46:7, 46:16, 46:21, 48:9, 48:12, 51:3, 51:17, 53:15, 53:18, 54:8, 54:18, 55:11, 55:24, 56:5, 56:24, 57:13, 57:19, 58:1, 58:7, 59:16, 60:21, 63:12, 63:14, 65:17, 65:20, 65:21, 67:12, 67:15, 67:20, 67:21, 67:22, 68:1, 68:24, 69:1, 69:9, 69:11, 69:12, 69:13, 70:21, 71:15, 71:22, 74:6, 75:3, 75:10, 75:14, 75:22, 76:4, 77:14, 78:9, 78:15, 78:20, 80:7, 80:15, 80:22, 82:17, 82:22, 83:1, 85:10, 95:20, 96:1, 96:5, 96:7, 96:9, 96:12, 96:18, 96:21, 96:25, 97:6, 97:9, 97:15, 97:16, 97:18, 99:1, 99:4, 102:12, 102:19, 105:6, 105:18, 114:11, 114:16, 114:18, 118:25, 119:3, 119:6, 119:7, 119:14, 119:16, 121:1, 139:15, 140:1, 140:7, 140:8, 140:13, 143:4, 153:9, 153:11, 153:23, 153:25,</p>	<p>154:23, 154:25, 155:2, 155:5, 161:18, 167:12, 168:1, 168:11, 168:24, 169:16, 169:23, 170:15, 170:25, 171:4, 171:6, 171:10, 174:7, 174:10, 174:17, 175:2, 175:10, 179:22, 182:4, 182:7, 182:11, 182:13, 205:11, 209:5, 209:7, 209:22, 211:22, 212:1, 212:5, 212:22, 213:9, 213:13, 214:13, 214:17, 214:20, 215:20, 222:10, 224:8, 224:16, 224:20, 225:7, 225:20, 226:1, 226:5, 226:8, 226:10, 226:11, 226:12, 227:1, 227:7, 227:12, 227:14, 227:15, 227:16, 227:19, 234:19, 234:23, 234:25, 242:6, 242:10, 243:9, 243:12, 243:13, 243:17, 243:25, 244:12, 244:17, 244:20, 245:5 theft [1] - 221:11 themselves [2] - 124:11, 183:20 theoretical [1] - 231:15 theory [3] - 213:1, 213:6, 244:8 therapeutic [1] - 189:14 thereafter [1] - 26:13 therefore [6] - 23:5, 77:23, 78:7, 147:24, 148:1, 174:24 thinking [1] - 198:24 third [8] - 74:21, 188:2, 195:19, 202:17, 204:15, 211:8, 217:21, 240:13 Thomas [1] - 2:12 thoroughly [1] - 12:7 thousand [6] - 103:13, 139:25, 140:14, 179:16, 181:9,</p>	<p>181:10 threat [1] - 216:13 Three [1] - 6:5 three [10] - 6:12, 22:17, 23:20, 41:24, 48:18, 60:5, 64:20, 161:23, 181:19, 188:6 throughout [4] - 59:7, 72:22, 180:18, 225:18 thus [1] - 94:18 tightly [1] - 232:3 timeline [1] - 217:10 timely [1] - 132:9 timing [2] - 36:6, 215:2 TIMOTHY [1] - 5:9 tiny [1] - 104:25 Title [1] - 93:3 title [2] - 228:3, 231:20 titled [2] - 188:1, 191:4 titles [1] - 231:11 today [14] - 101:21, 122:5, 154:12, 158:20, 167:4, 182:16, 183:25, 186:25, 191:19, 201:17, 226:22, 227:5, 228:8, 232:11 together [10] - 99:6, 128:2, 149:16, 154:8, 179:19, 189:16, 193:10, 211:4, 225:17, 225:18 tomorrow [8] - 226:22, 227:3, 227:5, 243:8, 243:10, 244:21, 244:23 took [17] - 7:18, 9:12, 16:3, 17:14, 17:20, 20:6, 20:24, 65:1, 99:12, 117:14, 119:24, 142:21, 142:22, 143:1, 143:14, 149:24, 214:25 tools [1] - 237:9 top [10] - 10:5, 42:1, 42:2, 42:3, 42:4, 103:22, 144:7, 187:15, 215:4 topic [2] - 94:14, 211:5 topics [1] - 85:16 Total [1] - 215:5 total [5] - 132:21,</p>	<p>133:14, 134:3, 134:5, 206:6 touch [1] - 212:1 touched [2] - 85:16, 206:13 Tower [2] - 3:4, 4:18 town [1] - 103:12 towns [1] - 104:25 tox [1] - 159:24 toxicological [1] - 167:3 toxicologist [1] - 166:3 toxicologists [1] - 155:25 toxicology [18] - 123:4, 123:5, 123:8, 125:12, 134:17, 134:23, 134:25, 135:1, 143:17, 159:21, 175:5, 175:8, 188:21, 188:24, 189:3, 189:8, 218:11, 218:13 track [3] - 31:18, 104:16, 159:10 tracked [3] - 143:16, 149:25, 150:1 tracking [1] - 197:9 tracks [1] - 217:4 trafficking [1] - 155:22 trained [4] - 7:19, 123:9, 162:10, 162:11 trainees [1] - 7:20 training [13] - 7:24, 8:3, 8:9, 8:11, 8:15, 103:17, 103:25, 104:7, 104:9, 104:15, 106:25, 122:25, 125:10 Training [1] - 101:14 trajectory [2] - 195:23, 196:5 transaction [2] - 238:11, 240:14 transactions [2] - 25:20, 240:16 transcript [2] - 6:19, 246:4 transient [1] - 197:12 transmission [1] - 98:12 transmitted [1] - 35:6 transparency [1] - 33:13 travel [2] - 244:23, 245:2 traveling [1] - 113:9</p>	<p>treat [2] - 106:8, 107:4 treated [2] - 94:9, 178:4 treating [3] - 98:10, 108:4, 108:5 treatment [2] - 83:7, 112:5 treats [1] - 98:11 trend [11] - 127:11, 137:22, 158:14, 204:7, 204:18, 204:22, 205:2, 205:3, 210:12, 210:15, 218:7 trending [1] - 115:7 trends [12] - 114:9, 114:13, 115:6, 115:12, 131:16, 191:20, 191:22, 198:6, 199:4, 204:18, 211:3 TRIAL [1] - 1:16 Trial [1] - 245:6 trial [1] - 225:19 tribes [1] - 107:25 trickle [1] - 220:7 tried [3] - 108:22, 128:21, 130:20 triggered [1] - 23:10 trouble [5] - 128:15, 133:5, 181:21, 226:15, 226:17 true [10] - 36:16, 38:4, 68:1, 90:15, 92:25, 93:11, 139:8, 237:20 trust [1] - 185:23 truth [1] - 57:23 try [12] - 67:4, 67:8, 74:24, 85:15, 110:6, 121:4, 145:11, 153:11, 174:13, 196:20, 197:20, 223:5 trying [13] - 55:21, 67:10, 77:25, 78:4, 83:13, 130:21, 153:12, 167:1, 170:4, 170:15, 175:7, 213:7, 216:25 turn [29] - 25:5, 29:3, 40:15, 41:17, 42:1, 42:21, 46:24, 48:22, 49:18, 50:20, 51:22, 58:5, 63:18, 63:24, 64:5, 67:18, 70:6, 70:9, 79:15, 148:18, 175:25, 180:9, 187:13, 190:25, 193:14, 193:16, 195:11, 196:25,</p>
---	---	--	---	---

<p>220:23</p> <p>TV ^[1] - 161:16</p> <p>Twelfth ^[3] - 4:13, 4:15, 5:5</p> <p>two ^[36] - 11:9, 11:14, 18:7, 21:6, 25:19, 26:6, 26:25, 28:11, 28:16, 33:16, 45:21, 49:1, 60:4, 60:6, 91:15, 103:12, 117:5, 119:7, 124:15, 133:22, 133:25, 147:11, 151:5, 153:3, 159:4, 163:22, 175:11, 181:19, 189:16, 207:19, 216:3, 216:23, 230:22, 242:8, 242:12, 243:21</p> <p>two-hour ^[1] - 119:7</p> <p>tying ^[1] - 169:21</p> <p>type ^[12] - 12:6, 15:13, 15:25, 109:16, 121:12, 125:18, 167:20, 174:18, 215:16, 217:2, 217:16</p> <p>types ^[5] - 117:6, 125:3, 144:18, 179:7, 235:12</p> <p>typical ^[1] - 122:4</p> <p>typically ^[1] - 240:4</p> <p>Typically ^[1] - 235:10</p>	<p>233:21, 234:1, 234:3</p> <p>underlying ^[4] - 158:24, 164:21, 198:19, 198:20</p> <p>underneath ^[1] - 38:8</p> <p>understood ^[2] - 51:20, 71:20</p> <p>undertaken ^[1] - 20:21</p> <p>undertook ^[2] - 20:9, 20:21</p> <p>unfair ^[1] - 68:22</p> <p>unfortunately ^[2] - 117:20, 226:18</p> <p>Unintentional ^[3] - 144:2, 192:4, 220:14</p> <p>unintentional ^[8] - 144:17, 147:15, 147:16, 148:2, 183:3, 192:24, 220:19, 220:21</p> <p>unintermediated ^[1] - 238:7</p> <p>unique ^[1] - 132:8</p> <p>UNITED ^[2] - 1:1, 1:17</p> <p>United ^[16] - 7:2, 47:9, 55:14, 89:19, 89:23, 90:4, 90:7, 90:18, 95:12, 104:2, 104:4, 180:18, 191:6, 192:25, 197:9, 220:19</p> <p>universities ^[1] - 109:10</p> <p>University ^[15] - 88:25, 97:24, 101:8, 103:9, 103:15, 108:16, 110:3, 111:4, 228:2, 228:3, 229:4, 229:16, 232:17, 234:2, 234:10</p> <p>university ^[2] - 89:5, 228:25</p> <p>University's ^[1] - 109:12</p> <p>unless ^[6] - 18:14, 26:14, 28:22, 65:19, 118:24, 163:2</p> <p>unlike ^[1] - 162:21</p> <p>unreconciled ^[1] - 27:16</p> <p>unreliable ^[1] - 223:8</p> <p>unscrupulous ^[1] - 85:1</p> <p>untestable ^[2] - 55:9, 55:10</p> <p>untrained ^[1] - 85:1</p> <p>up ^[106] - 8:19, 13:1, 13:16, 18:24, 19:1, 27:2, 29:9, 30:19,</p>	<p>33:10, 33:15, 37:20, 37:23, 38:21, 40:14, 41:22, 42:23, 47:21, 53:15, 60:8, 63:16, 67:2, 68:11, 69:6, 70:2, 72:15, 77:12, 77:25, 79:13, 81:21, 82:10, 83:7, 83:17, 83:23, 83:25, 85:18, 87:4, 87:8, 87:24, 88:4, 91:7, 91:10, 95:7, 98:7, 103:11, 107:13, 110:15, 113:5, 117:8, 117:13, 119:16, 122:6, 124:18, 127:7, 127:8, 127:17, 128:18, 130:11, 131:5, 131:21, 133:3, 134:22, 136:11, 137:4, 137:20, 138:24, 143:22, 145:21, 149:15, 153:12, 155:1, 155:12, 158:7, 159:15, 164:14, 167:21, 169:7, 183:17, 188:20, 188:24, 189:8, 194:18, 195:7, 198:11, 199:6, 200:1, 205:17, 209:9, 210:25, 211:1, 211:10, 217:20, 218:17, 218:22, 219:15, 219:21, 226:20, 226:25, 227:12, 228:10, 234:11, 239:18, 243:8, 243:16, 244:15, 244:23</p> <p>upper ^[3] - 95:7, 147:8, 171:19</p> <p>ups ^[2] - 204:24</p> <p>urban ^[4] - 215:6, 216:4, 216:8, 216:10</p> <p>urine ^[1] - 218:19</p> <p>USC ^[1] - 48:1</p> <p>useful ^[2] - 27:25, 228:10</p> <p>uses ^[2] - 84:24, 129:17</p> <p>utilize ^[1] - 113:10</p> <p>utilized ^[1] - 112:16</p>	<p>134:16, 213:5</p> <p>validated ^[1] - 145:24</p> <p>validating ^[1] - 243:4</p> <p>Valium ^[1] - 207:17</p> <p>Valley ^[3] - 230:17, 230:24, 234:16</p> <p>value ^[1] - 225:25</p> <p>variation ^[1] - 205:1</p> <p>variations ^[2] - 59:5, 59:6</p> <p>variety ^[1] - 99:24</p> <p>various ^[7] - 47:20, 100:3, 100:20, 108:9, 112:7, 116:11, 133:15</p> <p>vast ^[4] - 112:8, 114:22, 127:24, 147:17</p> <p>vehicle ^[1] - 109:22</p> <p>Ventura ^[1] - 3:18</p> <p>venture ^[1] - 89:17</p> <p>verbatim ^[1] - 20:11</p> <p>version ^[12] - 31:25, 50:17, 59:5, 59:13, 60:1, 168:6, 168:9, 168:23, 171:3, 171:7, 174:5, 174:8</p> <p>versus ^[2] - 126:15, 170:7</p> <p>vett ^[1] - 39:1</p> <p>via ^[1] - 14:18</p> <p>view ^[5] - 25:9, 61:18, 61:23, 89:12, 89:13</p> <p>violate ^[5] - 84:22, 92:22, 93:2, 93:7, 93:13</p> <p>violation ^[1] - 84:4</p> <p>Virginia ^[91] - 4:18, 7:3, 23:2, 97:24, 98:4, 100:24, 104:19, 106:14, 108:15, 108:19, 108:23, 109:8, 109:15, 109:18, 110:5, 110:22, 110:23, 111:15, 112:14, 113:2, 113:3, 113:21, 114:9, 114:14, 115:3, 118:1, 121:25, 122:9, 122:17, 123:4, 123:16, 123:20, 124:4, 127:13, 128:16, 129:12, 131:17, 131:24, 132:20, 136:6, 142:1, 144:12, 145:1, 145:9, 146:6, 147:13, 148:14,</p>	<p>148:21, 150:4, 150:6, 150:13, 151:14, 152:16, 152:25, 153:22, 154:15, 156:11, 157:3, 160:3, 161:12, 161:21, 167:18, 170:2, 170:3, 173:9, 174:15, 175:15, 181:17, 183:4, 183</p>
---	--	--	--	--

WEBB ^[1] - 3:11 Webb ^[1] - 3:12 website ^[8] - 33:9, 33:10, 33:15, 59:21, 59:22, 79:9, 80:10, 150:7 week ^[1] - 227:6 weekend ^[1] - 245:2 weeks ^[1] - 25:10 weight ^[1] - 112:17 welcome ^[1] - 32:6 well-documented ^[1] - 142:8 well-known ^[1] - 231:13 west ^[1] - 234:10 West ^[96] - 7:3, 23:1, 97:24, 98:4, 100:24, 104:18, 106:14, 108:15, 108:19, 108:23, 109:8, 109:15, 109:17, 110:4, 110:7, 110:21, 110:23, 111:14, 112:14, 113:2, 113:3, 113:21, 114:9, 114:14, 115:3, 118:1, 121:25, 122:9, 122:17, 123:4, 123:16, 123:20, 124:4, 127:13, 128:15, 129:12, 131:17, 131:24, 132:20, 136:6, 142:1, 144:11, 145:1, 145:8, 146:6, 147:13, 148:14, 148:21, 150:4, 150:6, 150:13, 151:14, 152:16, 152:25, 153:22, 154:15, 156:11, 157:2, 160:3, 161:12, 161:20, 167:17, 170:2, 170:3, 173:8, 174:15, 175:15, 181:17, 183:3, 183:14, 183:23, 186:2, 186:7, 186:9, 186:11, 188:4, 188:13, 191:1, 191:7, 194:7, 194:24, 195:8, 195:15, 196:2, 196:18, 198:1, 198:5, 199:14, 217:17, 220:18,	220:21, 221:8, 221:14, 222:3, 241:1 WEST ^[2] - 1:1, 1:18 WESTFALL ^[6] - 13:18, 14:1, 15:10, 55:14, 96:19, 96:23 Westfall ^[1] - 13:24 whatsoever ^[1] - 96:21 wheels ^[1] - 119:3 whereas ^[1] - 198:17 white ^[1] - 215:5 whole ^[23] - 37:8, 45:16, 60:8, 60:24, 84:17, 106:3, 106:8, 113:12, 116:5, 128:19, 128:25, 133:2, 133:14, 145:24, 147:24, 150:15, 156:12, 157:24, 179:16, 179:20, 181:11, 216:5, 240:12 wholesale ^[3] - 34:11, 34:25, 162:21 wholesaler ^[1] - 14:17 Wicht ^[5] - 72:16, 78:9, 80:15, 82:17, 95:20 WICHT ^[7] - 4:12, 78:10, 80:16, 82:18, 95:21, 96:11, 234:22 widespread ^[1] - 221:8 wife ^[1] - 104:11 Williams ^[2] - 4:13, 5:4 win ^[2] - 232:4 win-win ^[1] - 232:4 winning ^[2] - 231:16, 231:25 Wisconsin ^[1] - 229:16 Wisconsin-Madison ^[1] - 229:16 wish ^[1] - 182:10 withdraw ^[1] - 171:10 withdrawn ^[1] - 71:21 witness ^[22] - 7:5, 56:3, 57:24, 68:14, 68:19, 77:22, 90:6, 90:12, 96:12, 96:15, 97:1, 102:9, 102:11, 114:7, 114:12, 140:4, 140:5, 170:22, 205:15, 211:24, 212:24, 226:20 WITNESS ^[34] - 7:15, 8:24, 19:6, 44:5,	45:9, 63:14, 65:17, 65:20, 67:21, 69:9, 69:12, 76:4, 96:7, 97:9, 97:12, 97:16, 97:18, 99:1, 99:4, 105:6, 105:18, 114:18, 119:6, 121:1, 140:7, 140:13, 153:25, 182:11, 213:13, 226:11, 227:15, 227:18, 234:25, 243:12 witnesses ^[3] - 48:7, 102:8, 205:5 WOELFEL ^[1] - 3:9 Woelfel ^[2] - 3:9 women ^[2] - 146:20, 161:15 won ^[1] - 232:14 wondering ^[1] - 103:10 wonders ^[1] - 236:12 Woodworth ^[4] - 53:4, 53:11, 53:24, 54:2 word ^[9] - 21:24, 87:5, 103:22, 160:10, 184:21, 210:19, 217:22, 218:22, 219:1 wording ^[1] - 160:10 words ^[4] - 21:13, 26:10, 84:25, 220:5 workplace ^[3] - 107:3, 107:4 works ^[5] - 8:1, 18:24, 34:7, 73:18, 235:15 world ^[4] - 103:24, 107:23, 125:21, 148:16 World ^[1] - 100:16 Worm ^[1] - 105:2 worth ^[1] - 114:16 wrap ^[1] - 153:12 wrestling ^[1] - 209:15 Wright ^[2] - 9:16, 49:9 write ^[2] - 123:12, 197:8 written ^[4] - 14:25, 26:15, 110:3, 242:18 wrongly ^[1] - 52:20 wrote ^[3] - 17:7, 73:5, 101:2 Wu ^[8] - 140:1, 153:9, 155:8, 170:16, 182:4, 206:13, 221:1, 225:20 WU ^[51] - 5:10, 102:7, 140:3, 153:8, 153:10, 154:24,	155:1, 155:4, 155:7, 161:19, 167:9, 167:13, 167:24, 168:5, 168:13, 168:22, 169:6, 169:11, 169:19, 170:11, 170:18, 171:2, 171:5, 171:8, 171:12, 171:13, 174:1, 174:8, 174:21, 175:4, 175:13, 175:14, 179:21, 179:23, 182:6, 182:14, 182:15, 191:1, 191:3, 194:18, 194:20, 199:6, 199:9, 211:21, 211:23, 215:18, 222:11, 222:13, 224:17, 225:4, 225:21 wu ^[1] - 154:23 WV ^[7] - 2:8, 3:10, 3:13, 4:19, 5:15, 6:9, 32:25 WVU ^[3] - 101:5, 103:5, 108:22 Wyoming ^[1] - 111:24	Yesterday ^[1] - 242:10 yesterday ^[18] - 31:17, 32:9, 32:10, 37:1, 40:17, 40:20, 41:20, 54:24, 58:16, 59:25, 60:16, 62:13, 67:23, 68:2, 73:22, 83:6, 83:12, 84:15 York ^[2] - 3:5, 216:8 young ^[2] - 129:21, 218:10 yourself ^[6] - 97:22, 121:16, 125:8, 164:20, 227:24, 235:22
Z				
Zealand ^[2] - 103:9, 103:11 Zhang ^[1] - 192:3 Zimmerman ^[6] - 33:25, 34:8, 34:23, 35:10, 62:15, 79:10 Zimmerman's ^[1] - 35:14 Zoom ^[1] - 155:9				
X				
Xanax ^[1] - 207:15				
Y				
year ^[17] - 27:2, 103:17, 104:10, 107:19, 108:2, 128:25, 137:21, 146:18, 174:16, 183:15, 194:4, 202:3, 204:11, 223:6, 232:9, 233:6 yearly ^[2] - 8:4, 62:10 years ^[33] - 26:12, 27:11, 28:18, 28:20, 52:9, 55:3, 101:15, 101:18, 108:19, 127:21, 138:8, 146:8, 146:16, 146:20, 152:22, 152:25, 181:19, 197:16, 197:17, 198:11, 199:22, 202:12, 202:21, 204:21, 210:4, 216:14, 220:18, 229:9, 230:22, 232:22, 233:3, 234:13				